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## **FORM 10-K**

**SEQUENOM INC - SQNM**

**Filed: March 09, 2012 (period: December 31, 2011)**

Annual report with a comprehensive overview of the company

**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, 2011**

OR

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

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_**

**Commission File Number: 000-29101**

**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)

**77-0365889**

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

**92121**

(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  No

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, 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)

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, 2011 as reported on The NASDAQ Global Select Market, was approximately \$646.1 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 March 2, 2012, there were 114,537,240 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 11, 2012. Such definitive proxy statement will be filed with the Commission no later than 120 days after December 31, 2011.

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**FORM 10-K**  
**For the Fiscal Year Ended December 31, 2011**  
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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-looking 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®, Sequenom Center for Molecular Medicine®, SpectroCHIP®, iPLEX®, SensiGene®, and MassARRAY® are registered trademarks and SEQuireDx®, iSEQ™, RetnaGene™, MaterniT21™, and MaterniT21™ PLUS 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,” the “Company,” 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 molecular diagnostic testing services, and research use only 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, and other medical conditions such as oncology, infectious diseases and autoimmunity.

#### Operating Segments

We operate our business on the basis of two reportable segments, Molecular Diagnostics (including Sequenom Center for Molecular Medicine, LLC, or Sequenom CMM) and Genetic Analysis. A further description of the operations of these segments is below. For the years ended December 31, 2011, 2010, and 2009, we generated approximately 85.1%, 94.6%, and 99.8%, respectively, of our revenues from our Genetic Analysis segment. Product sales and services revenues for this segment were derived from sales of consumables, including our SpectroCHIP arrays used with our iPLEX assay and other assays, MassARRAY systems, maintenance agreements, sales and licensing of our proprietary software, and contract research services. Diagnostic revenues accounted for approximately 14.9%, 5.4%, and 0.2% of our revenues for the years ended December 31, 2011, 2010, and 2009, respectively, and were primarily derived from the sale of Sequenom CMM’s Cystic Fibrosis, or CF, Carrier Screening laboratory-developed test, or LDT, and to a much lesser extent the Rhesus D, or RHD, genotyping LDT. Collections from the sale of Sequenom CMM’s age-related macular

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degeneration, or AMD, LDT and MaterniT21 LDT were not significant for the periods presented due to commencement of their commercialization in the second and fourth quarters of 2011, respectively. Revenue for Molecular Diagnostics is generated from customers located in the United States. Revenue for Genetic Analysis is generated from customers and/or distributors located in North America, Europe, and Asia.

We evaluate segment performance based on a revenue and operating income (loss) basis exclusive of general and administrative expenses, stock-based compensation, litigation settlement expense, other indirect costs, and certain other adjustments, which are not allocated to our segments for performance assessment by our chief operating decision maker. Unallocated operating expenses excluded from our segments for performance assessment represent expenses that do not reflect, according to criteria established by us, operating expenses associated with our reportable segment activities. No evaluation of segment performance or allocation of resources is done by our chief operating decision maker in consideration of discrete segment assets and we do not discretely allocate assets to our operating segments. Intersegment revenues and transfers are immaterial. The accounting policies of the reportable segments are the same as those described in the summary of significant accounting policies.

The following table sets forth our revenues and operating loss from our Molecular Diagnostic (including Sequenom CMM) and Genetic Analysis segments for the years ended December 31, 2011, 2010, and 2009, (in thousands):

	2011	2010	2009
Revenues:			
Molecular diagnostics	\$ 8,319	\$ 2,554	\$ 94
Genetic analysis	47,588	44,905	37,769
Total revenues	<u>\$ 55,907</u>	<u>\$ 47,459</u>	<u>\$ 37,863</u>
Operating (loss) gain:			
Molecular diagnostics	\$(43,799)	\$(36,216)	\$(27,034)
Genetic analysis	14,216	11,873	4,379
Unallocated	(44,681)	(96,676)	(48,067)
Total operating loss	<u>\$(74,264)</u>	<u>\$(121,019)</u>	<u>\$(70,722)</u>

### Molecular Diagnostics and SEQuereDx 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, and other medical conditions such as oncology, infectious diseases, and autoimmunity. Currently, we are primarily focused on developing and commercializing prenatal diagnostic tests using our foundational, patent-protected, noninvasive, circulating cell-free fetal, or cff, nucleic acid-based assay technology, which we in-license from Isis Innovation Limited, or Isis. This technology uses a maternal blood sample for a prenatal diagnosis or risk assessment in order to provide reliable information about the presence, amount, or absence of fetal genetic material in early pregnancy. We have branded our technology for prenatal diagnostics under the trademark SEQuereDx. 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 execute 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 in the United States of certain of our *in vitro* diagnostic tests where we believe it will afford us competitive advantages to do so, such as providing us with the flexibility to sell the tests as FDA cleared *in vitro* diagnostic (IVD) kits to other laboratories, and an alternative in the event the FDA decides to exercise its enforcement jurisdictional authority with respect to regulation of laboratory-developed tests as *in vitro* diagnostics. Historically, the FDA has exercised enforcement discretion and exempted from regulation

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LDTs, but the FDA has stated that additional regulation of LDTs may be warranted. In 2010 we submitted a pre-investigational device exemption submission and supplements 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 designs.

Sequenom Center for Molecular Medicine

Sequenom CMM is our wholly-owned subsidiary, and operates a laboratory located in Grand Rapids, Michigan, and a second laboratory located in San Diego, California, that are both 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, of 1988, as amended, or CLIA. Sequenom CMM develops and validates LDTs for use in and solely by Sequenom CMM as a testing service to physicians. Sequenom CMM utilizes our patented SEQuEDx cff technology in developing some of its LDTs. Sequenom CMM has validated and currently offers to physicians four LDTs: MaterniT21 PLUS LDT to determine the relative amounts of chromosome 21, 18, and 13 material present as circulating cell-free DNA in a maternal blood sample; SensiGene RHD Genotyping to determine a mother's blood type and Rhesus D (RhD) factor; SensiGene Cystic Fibrosis Carrier Screening to help identify individuals who may have an increased risk of having certain cystic fibrosis, or CF, genetic mutations; and RetnaGene AMD to predict genetic predisposition to develop late-stage (wet) age-related macular degeneration, or AMD. Patient samples are collected by physicians and submitted to Sequenom CMM for testing and the results are reported back to the ordering physician.

In February 2012, the MaterniT21 test was rebranded under the name MaterniT21 PLUS and the expanded test includes detection of any increased representation of either chromosome 18 or 13 material (associated with trisomy 18 and 13, respectively), in addition to chromosome 21 material (associated with trisomy 21). The results of an independent multi-center study demonstrating the performance of the test was published online on February 2, 2012 by our academic collaborators in the journal *Genetics in Medicine*.

We have invested substantially in Sequenom CMM's information technology infrastructure to enhance the capabilities of the laboratories to track samples and provide electronic ordering and reporting and have put in place sample collection and transportation logistics that can be scaled as demand for Sequenom CMM's molecular diagnostic testing services increases. Currently, we offer pricing on our diagnostic testing services that address the following general parameters: Insured patients have established maximum out-of-pocket costs with the payor being billed at the full list price and any outstanding amounts due are pursued from the payor, not the patient, on appeal. Uninsured patients are billed using a separately maintained price list. Due to our current out-of-network provider status associated with the lack of existing contracts with payors and the current level of adoption rates, we expect amounts billed will fluctuate until these factors are resolved. Sequenom CMM intends to provide reimbursement recommendations and enter into contracts with third-party payors to establish contractual pricing for its LDTs.

Sequenom CMM developed, analytically validated, clinically validated in a large multi-center international blinded study, and in October 2011, commercialized the MaterniT21 LDT for testing pregnant women who are at increased risk (by medical and clinical indicators) of carrying a fetus with trisomy 21. The MaterniT21 LDT analyzes circulating cell-free DNA extracted from a maternal blood sample utilizing massively parallel sequencing. The test detects increased representation of chromosome 21 material, which is associated with trisomy 21. Sequenom CMM performs the MaterniT21 LDT on a massively parallel sequencing platform (HiSeq 2000), which it believes is commercially attractive compared to other platforms because of technological advances and steadily declining projected instrument and reagent costs of massively parallel sequencing. The MaterniT21 LDT is a noninvasive testing service that Sequenom CMM has demonstrated in a published large scale pivotal clinical validation study to have high specificity and sensitivity compared to currently available serum biochemical screening tests, can be used during the first and second trimesters of pregnancy, has broad ethnic coverage of the global population, and is a direct genetic test, not a surrogate marker.

In November 2010, Sequenom CMM presented the results from a pilot 96 patient study of a trisomy 21 test using massively parallel sequencing at a meeting of the American Society of Human Genetics. Based on the

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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 was published online on February 10, 2011, in the American Journal of Obstetrics & Gynecology.

Based on the results from these two studies, Sequenom CMM undertook a large pivotal clinical validation study. The study was sponsored by Sequenom, but was designed, implemented, analyzed, and reported by researchers at Women & Infants Hospital / Alpert School of Medicine of Brown University in Rhode Island, and was an independent multi-center international collaboration. In this study, Sequenom CMM tested and analyzed patient samples that had been collected under an institutional review board-approved clinical study conducted under the auspices of the Women & Infants Hospital in Rhode Island. The total number of patient samples in the clinical validation study was approximately 2,000, of which more than 200 were positive for trisomy 21 based on laboratory confirmation of the diagnosis performed on patient samples obtained from chorionic villus sampling, or genetic amniocentesis. The study design called for approximately 100 positive samples in each of the first and second trimesters of pregnancy. Sequenom CMM used essentially the same assay process in the clinical validation study that was used in the 480 sample study with the exception of employing the higher throughput Illumina HiSeq 2000, a second generation sequencer, introduced in 2010. Sequenom CMM scientists previously completed equivalency studies on the HiSeq 2000 sequencer in preparation for this large pivotal clinical validation study. This large pivotal clinical validation study was published online on October 17, 2011 by our academic collaborators in the journal Genetics in Medicine.

#### 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 was 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 cleared or approved by the FDA. 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. We 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.

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 upon genetic tests that have not undergone the FDA's premarket review. 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 at that time it had no further questions on the direct-to-consumer issue.

#### **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 cff 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 cff 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

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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 made up-front payments to Isis and agreed to 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 uncurd 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 Agreements***

In May 2011, we entered into a License Agreement with The Chinese University of Hong Kong, or CUHK, pursuant to which CUHK granted us an exclusive, worldwide (excluding Hong Kong), royalty-bearing license to use, and to sublicense, certain intellectual property covered by patent applications owned by CUHK for prenatal diagnostics, prognostics, and analysis for research and commercial purposes. This license agreement covers intellectual property rights relating to size-based genomic analysis. Pursuant to this license agreement we paid an upfront license fee to CUHK of \$1,500,000 and are obligated to pay an additional \$1,500,000 within one year. Because we consider the technology to still be in the research and development phase and to have no alternative future uses, we recorded the upfront license fee of \$3.0 million as research and development expense in 2011. We are obligated to pay royalties on sales of products incorporating the licensed intellectual property and amounts we receive from any sublicensees. We are also obligated to pay additional amounts to CUHK upon the accomplishment of certain development and commercialization milestones. If we fail to achieve certain development and commercialization milestones within specified timeframes, CUHK may terminate this license agreement. In accordance with this license agreement, CUHK will prosecute, defend and maintain certain patent applications relating to the licensed intellectual property at our expense. This license agreement will expire on the later of 20 years or the expiration of the last patent, if any patent is issued, relating to the licensed intellectual property, unless terminated earlier pursuant to the terms of this license agreement. We may terminate this license agreement at any time after one year on 30 days written notice to CUHK.

In May 2011, pursuant to this license agreement, we issued to The Chinese University of Hong Kong Foundation Limited (an affiliate of CUHK) a warrant to purchase up to 200,000 shares of our common stock at a price of \$7.00 per share, the closing price of our common stock on May 3, 2011. The warrant was immediately exercisable, in whole or in part, but not for less than 20,000 shares and in increments of 20,000 shares, has a term of seven years, and was valued at \$1.2 million using the Black-Scholes pricing model, which we recorded as research and development expense in 2011.

We have also exclusively in-licensed patent rights from 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 massively parallel sequencing. 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 massively parallel sequencing, are non-exclusive. Under this 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

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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, worldwide license to certain of our in-licensed patent rights, which do not relate to prenatal diagnostic testing by massively parallel sequencing. Under this agreement, 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.

This 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.

This 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 sublicensee 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 massively parallel sequencing 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***

In July 2011, we entered into a Sale and Supply Agreement with Illumina, Inc., or Illumina, which we amended in September 2011, pursuant to which we and our subsidiaries will purchase laboratory equipment and consumables that will be used for our fetal chromosomal detection applications, including a noninvasive test which is designed to detect an overabundance of chromosome 21 in pregnant women, a result associated with fetal Down syndrome. This agreement requires that we submit periodic binding forecasts for consumables. Beginning in 2013, in the event that we purchase less than a specified amount of consumables during any calendar year, Illumina will be relieved of certain of its obligations and representations under the agreement,

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including certain of Illumina's obligations with respect to pricing terms of the consumables that we purchase. Additionally, we and Illumina have agreed to work collaboratively toward our submission for regulatory approval of an in vitro diagnostic product for the detection of fetal chromosomal abnormalities. This agreement will remain valid for a three-year term, unless terminated earlier as provided for in the agreement. Either party may terminate the agreement prior to expiration for the uncured material breach of the agreement by the other party or upon the bankruptcy or insolvency of the other party.

### **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 estimated to be as follows:

- Each year in the United States there are approximately 528,000 Rhesus D negative women who are pregnant and could benefit from assessments of the RhD status of their fetuses. Our test addresses a portion of this market.
- There are a number of tests available for cystic fibrosis carrier screening. In the United States about 1.1 million tests are performed annually and the average cost of these tests is between \$200 and \$400 per test.
- For prenatal trisomy testing in the high-risk pregnancy (based on factors including advanced maternal age, personal or family history, results from other clinical tests) patient population of the market (to which our MaterniT21 PLUS test is currently directed) in the United States, we estimate the available market for a noninvasive trisomy 21 test (and including trisomies 18 and 13) to be approximately 750,000 patients per year.
- AMD affects 15-20 million people in the United States, 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, and 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, bioagriculture, biotechnology 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 employees serving North America, Europe and Asia, in addition to utilizing sales and 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-

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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 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 potential 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, and linkage 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

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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 is recognized by plant crop researchers who 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 that 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 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 and market growth for our current offerings. 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, and other medical conditions such as oncology, infectious diseases and autoimmunity. 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 LDTs in prenatal, women's health, and ophthalmology medical conditions for use in and solely by the laboratory. In the second and fourth quarters of 2011 Sequenom CMM commercialized its AMD and MaterniT21 LDTs, respectively.

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 and diagnostic applications;
- Developing and commercializing noninvasive prenatal diagnostic assays and other proprietary tests for women's health, ophthalmology, and other medical conditions such as oncology, infectious diseases and autoimmunity;
- Expanding our diagnostic offerings through in-licensing, partnering and acquisitions; and
- Investing in our Sequenom CMM CAP-accredited and CLIA-certified laboratories to increase its capacity for making 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 518 issued or allowed patents and approximately 335 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 '540 patent and its foreign equivalents will expire in 2018. 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 appealed the EPO's decision (Appeal No. T146/07-334) and subsequently the Boards of Appeal of the EPO rejected the appellants arguments and dismissed the appeal and upheld the Patent.

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.

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

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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, Verinata Health Inc., and Stanford University have filed a complaint against us asserting infringement of United States Patent No. 7,888,017 titled "Non-invasive Fetal Genetic Screening by Digital Analysis", or the '017 patent, and United States Patent No. 8,008,018 titled "Determination of Fetal Aneuploidies by Massively Parallel DNA Sequencing", or the '018 patent, which include patent claims purportedly covering methods for the noninvasive detection of fetal aneuploidy. Challenging the validity of those patents and defending against claims of infringement of those patents, or if we have to defend against any other asserted intellectual property right, will be costly and divert management's attention and resources. As a result of such disputes, we may have to develop costly alternative 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**

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, some of our tests are based on detection of cff nucleic acid in maternal plasma. Our exclusive license to the intellectual property surrounding the use of cff 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 other sequencing approaches. Competitors and potential competitors include Ikonysis, Inc., Verinata Health, Inc. (formerly Artemis), Celula Inc., Fluidigm Corp., Aria Diagnostics, Inc. (formerly Tandem Diagnostics), Natera (formerly Gene Security Network, 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., 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, 2011, 2010, and 2009, were \$53.6 million, \$43.4 million, and \$37.5 million, respectively.

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During 2011, 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 2011, 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 development and commercialization of a noninvasive cff prenatal test for trisomy 21, completion of an LDT for AMD, development of improved or next generation tests, 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 may 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 LDTs are under the purview of the Centers for Medicare & Medicaid Services, or 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 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

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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 March 2, 2012, we employed 382 persons, of whom 56 hold Ph.D. or M.D. degrees and 74 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 9, 2012 are as follows:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Executive Officers		
Harry F. Hixson, Jr., Ph.D.	73	Chief Executive Officer and Director
Ronald M. Lindsay, Ph.D.	64	Executive Vice President, Research and Development and Director
Paul V. Maier, M.B.A.	64	Chief Financial Officer
Allan Bombard, M.D., M.B.A.	59	Chief Medical Officer
Charles R. Cantor, Ph.D.	69	Chief Scientific Officer
Alisa Judge	56	Vice President, Human Resources
Michael Monko, M.B.A.	52	Senior Vice President, Genetic Analysis
Clarke Neumann, J.D.	48	Vice President and General Counsel
Dirk van den Boom, Ph.D.	41	Senior Vice President, Research and Development
Robin Weiner, M.B.A.	56	Senior Vice President, Quality and Regulatory Affairs
William Welch, M.B.A.	50	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 our 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.

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*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 Arqule 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 and our CLIA/CAP Laboratory Director since June 2010. 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 since August 1998 and served as a member of our board of directors from 1998 to 2010. From 1992 to 2011, Dr. Cantor served as a professor in the Department of Biomedical Engineering and co-director of the Center for Advanced Biotechnology at Boston University and he is now professor emeritus. 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*. 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, DiThera, Inc., a biotechnology company that he founded in 2007, and Retrotrope, Inc. a biotechnology company that he founded in 2007. 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, from February 2003 to February 2005, Ms. Judge held the same role 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, genetic analysis since July 2011 and previously served as our senior vice president, sales and marketing since August 2006. Mr. Monko served as

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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.

*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, diagnostics, 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. Prior to Monogram, Mr. Welch was vice president of sales and marketing at La Jolla Pharmaceuticals and vice president of global marketing with Dade Behring MicroScan. Mr. Welch entered the healthcare field with Abbott Laboratories where he held progressive management positions, including General Manager. Mr. Welch holds a B.S. with honors 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](http://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](http://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

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 cease or reduce further commercialization efforts or 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 \$84.2 million as of December 31, 2011. On January 25, 2012, we closed an underwritten public offering of our common stock totaling 14,950,000 shares of our common stock at \$4.15 per share. The offering resulted in aggregate net proceeds of approximately \$58.2 million after deducting underwriting commissions and transaction expenses. 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 through 2013. Our and Sequenom CMM's announced plans to expand our operations to commercialize the MaterniT21 PLUS LDT and our research and development activities related to improvements to current tests and other LDTs and to expand our diagnostic test menu may require raising additional funds. In addition, there can be no assurances that our commercialization or research and development activities will be successful. We believe our current sales and marketing operations may not be sufficient to achieve the level of market awareness and sales required for us to attain significant commercial success for the MaterniT21 PLUS LDT. If we or Sequenom CMM are not able to successfully implement our marketing, sales and commercialization strategies, we and Sequenom CMM may not be able to expand geographically, increase sales of the MaterniT21 PLUS LDT or successfully commercialize any future LDTs or diagnostic tests that we may develop. Additionally, in order to execute our molecular diagnostic research and development activities, we need to collect a large number of patient samples in a timely manner. 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.

We anticipate that we may need to raise additional funds in the future to support commercialization of the MaterniT21 PLUS LDT and 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 commercialization efforts and our research and development programs, the status of ongoing litigation and the general condition of the financial markets. If we fail to raise additional funds, we will have to cease or reduce our commercialization efforts, 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;
- our success and our distributors' success in selling our MassARRAY system, ancillary reagents, software and services;

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- our and Sequenom CMM's success selling and marketing the MaterniT21 PLUS LDT and the level of collections and reimbursement from third-party payors;
- Sequenom CMM's success in generating revenues from its testing services for cystic fibrosis carrier screening, fetal Rhesus D genotyping, and AMD, and the level of reimbursement and collections for these and future tests;
- the terms and conditions of sales contracts, including extended payment terms;
- 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 and the acquisition and/or licensing of third-party intellectual property rights;
- 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 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 level of our legal expenses and any damages or settlement payments arising from ongoing or new patent related litigation;
- 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 not 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 U.S. Food and Drug Administration, or FDA, and other worldwide regulatory authorities; and
- technological developments in our markets.

General market conditions, the market price of our common stock, uncertainty about the successful commercialization of the MaterniT21 PLUS LDT and the development of other LDTs and diagnostic tests, regulatory developments, the uncertainty regarding the results of ongoing litigation matters 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,

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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.

***We and Sequenom CMM will need to expand our marketing and sales capabilities in order to increase demand for the MaterniT21 PLUS LDT, to expand geographically and to successfully commercialize any other diagnostic tests we may develop.***

In October 2011, Sequenom CMM began commercializing the MaterniT21 LDT, a noninvasive trisomy 21 test that analyzes DNA samples utilizing massively parallel sequencing. We believe our and Sequenom CMM's current sales and marketing operations are not sufficient to achieve the level of market awareness and sales required for us to attain significant commercial success for the MaterniT21 PLUS LDT, to expand our geographic presence and to successfully commercialize any other diagnostic tests we may develop. In order to increase sales of the MaterniT21 PLUS LDT, we will need to:

- expand our direct sales force in the United States by recruiting additional sales representatives in selected markets;
- enter into collaborative relationships with third parties to expand sales and marketing channels;
- educate clinicians, other healthcare professionals, clinical diagnostic laboratories, healthcare thought leaders and third-party payors regarding the clinical benefits and cost-effectiveness of the MaterniT21 PLUS LDT;
- expand our number of clinical diagnostic laboratory and hospital outreach laboratory customers; and
- establish, expand, and manage sales and reimbursement arrangements with third parties, such as insurance companies.

We have limited experience in selling and marketing the MaterniT21 PLUS LDT. We intend to hire a significant number of additional sales and marketing personnel with experience in the diagnostic, medical device or pharmaceutical industries. We may face competition from other companies in these industries, some of whom are much larger than us and who can pay significantly greater compensation and benefits than we can, in seeking to attract and retain qualified sales and marketing employees. If we are unable to hire and retain qualified sales and marketing personnel, our business will suffer. If we are not able to successfully implement our marketing, sales and commercialization strategies, we may not be able to expand geographically, increase sales of the MaterniT21 PLUS LDT or successfully commercialize any future diagnostic tests that we may develop.

***Uncertainty regarding the development of new LDTs could materially adversely affect our business, financial condition and results of operations.***

Sequenom CMM is continuing to focus research and development efforts on LDTs and diagnostic tests, other than the MaterniT21 PLUS LDT. The launch of any other 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 other 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

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complete clinical development for any planned molecular diagnostic test. Failure to possess or to collect a sufficient number of appropriate samples in a timely manner could prevent or significantly delay our ability to research, develop, complete clinical development and validation, obtain FDA clearance or approval as may be necessary, and launch, any of our planned tests. Any failure to complete our on-going clinical studies for our planned screening and diagnostic tests could have material adverse effects on our business, operating results or financial condition.

***We have been 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 had 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 also required us to produce information with respect to our announcements relating to our offer to acquire EXACT Sciences, Inc. in January 2009. 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. 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 was 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. On September 1, 2011, the SEC, pursuant to Section 21C of the Securities Exchange Act of 1934 entered a cease-and-desist order against us relating to our public statements made between June 2008 and January 2009 regarding our trisomy 21 test then under development. In accordance with the cease-and-desist order, we have agreed not to commit or to cause any future violations of 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, and monetary penalties were not imposed against us.

The investigations by the SEC, the U.S. Attorney and the FBI have had an adverse impact on our reputation. In the event that investigations by the SEC, the U.S. Attorney or the FBI lead to additional action against us or additional action against any current or former officer or director, our reputation, business prospects, operating results or financial condition may be adversely impacted. We have indemnification obligations to 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. If additional action is taken, 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.

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***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.***

In September 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 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 and must rely on technology provided by third parties in order to commercialize the MaterniT21 PLUS LDT, and may rely on third parties for commercialization of future products.***

Sequenom CMM's noninvasive prenatal and other molecular diagnostic LDTs are in 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 commercializing sequencing-based technology and rely on collaborative partners and sequencing technology provided by others in order to commercialize any test utilizing sequencing, including the MaterniT21 PLUS LDT. Among other risks, using a platform provided by another party presents potential manufacturing supply and reliability, quality compliance, and intellectual property infringement risks. For example, we have no control over the manufacture of the sequencers and consumables that Sequenom CMM is using for the MaterniT21 PLUS LDT, 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 need for the test.

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 new 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, including with respect to the MaterniT21 PLUS LDT;
- 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.

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Despite its ability to commercialize the MaterniT21 PLUS LDT, Sequenom CMM may face setbacks in the development and validation of other noninvasive prenatal and molecular diagnostic LDTs.

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 new 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.

***Failure to establish, and perform to, appropriate quality standards to assure that the highest level of quality is observed in the performance of our and Sequenom CMM's testing services and in the design, manufacture and marketing of products could adversely affect the results of our operations and adversely impact our reputation.***

The provision of clinical testing services, including the MaterniT21 PLUS LDT, and related services, and the design, manufacture and marketing of diagnostic products involve certain inherent risks. The services that we and Sequenom CMM provide and the products that we and Sequenom CMM design, manufacture and market are intended to provide information for healthcare providers in providing patient care. Therefore, users of such services and products may have a greater sensitivity to errors than the users of services or products that are intended for other purposes.

Manufacturing or design defects, unanticipated use of our or Sequenom CMM's products, or inadequate disclosure of risks relating to the use of the products can lead to injury or other adverse events. These events could lead to recalls or safety alerts relating to our products (either voluntary or required by governmental authorities) and could result, in certain cases, in the removal of a product from the market. Any recall could result in significant costs as well as negative publicity that could reduce demand for our or Sequenom CMM's products. Personal injuries relating to the use of our or Sequenom CMM's products can also result in product liability claims being brought against us. In some circumstances, such adverse events could also cause delays in new product approvals.

Similarly, negligence in performing our or Sequenom CMM's services can lead to injury or other adverse events. We or Sequenom CMM may be sued under physician liability or other liability law for acts or omissions by our or Sequenom CMM's laboratory personnel. We and Sequenom CMM are subject to the attendant risk of substantial damages awards and risk to our reputation.

***We may not be able to generate significant revenue from noninvasive prenatal diagnostic tests, including the MaterniT21 PLUS LDT, or any other tests we may develop.***

Our business is substantially dependent on our ability to develop and launch and obtain reimbursement for our diagnostic tests and Sequenom CMM LDTs, including the MaterniT21 PLUS LDT. Sequenom CMM has committed significant research and development resources for the development and validation of LDTs 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, including the MaterniT21 PLUS LDT, 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. In the second quarter of 2011, Sequenom CMM launched a testing service for assessment of risk for developing wet AMD. In October 2011, Sequenom CMM launched the MaterniT21 LDT. However, there is no guarantee that Sequenom CMM will be able to successfully

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launch other diagnostic testing services on anticipated timelines. We have limited experience in licensing, manufacturing, selling, marketing or distributing diagnostic 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 revenue from the sale of such tests or Sequenom CMM's LDT 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 significant revenue from the sale of such tests or testing services, including the following:

- 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 "Non-invasive Fetal Genetic Screening by Digital Analysis" and No. 8,8008,018 titled "Determination of Fetal Aneuploidies By Massive Parallel DNA Sequencing" assigned to Stanford University;
- parties infringing our intellectual property rights or operating outside 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 Clinical Laboratory Improvement Amendments, or CLIA, to process tests ordered by physicians;
- Sequenom CMM's ability to establish and maintain adequate infrastructure to support the commercialization of the MaterniT21 PLUS LDT and other testing services, 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;
- the level of 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;
- 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, including the MaterniT21 PLUS LDT;
- coverage and reimbursement levels by government payors and private insurers;
- the level of physician adoption of any diagnostic tests we or Sequenom CMM develop, including the MaterniT21 PLUS LDT;
- pricing pressures, lower prices offered by competitors, or changes in third-party payor reimbursement policies;

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- 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; and
- our ability to license and protect our SEQureDx patented technology and our other technologies.

***The diagnostic industry is subject to rapidly changing technology which could make the MaterniT21 PLUS LDT and other tests we are commercializing or developing obsolete unless we continue to develop and manufacture new and improved tests and pursue new market opportunities.***

Our industry is characterized by rapid technological changes, frequent new product introductions and enhancements and evolving industry standards, all of which could make the MaterniT21 PLUS LDT and the other LDTs we are commercializing or developing obsolete. Our future success will depend on our ability to keep pace with the evolving needs of our customers on a timely and cost-effective basis and to pursue new market opportunities that develop as a result of technological and scientific advances. These new market opportunities may be outside the scope of our expertise or in areas which have unproven market demand, and the utility and value of new tests that we develop may not be accepted in the market. Our inability to gain market acceptance of new tests could harm our future operating results. Further, if new research or clinical evidence or economic comparative evidence arises that supports alternative methods to test for trisomy 21, then demand for the MaterniT21 PLUS LDT could decline.

***The development of new, more cost-effective tests that can be performed by our customers or by patients, or the internalization of testing by hospitals or physicians, could negatively impact our testing volume and revenues.***

Advances in technology may lead to the development of more cost-effective tests that can be performed outside of a commercial clinical laboratory such as point-of-care tests that can be performed by physicians in their offices, esoteric tests that can be performed by hospitals in their own laboratories or home testing that can be performed by patients in their homes or by physicians in their offices. Although CLIA compliance costs make it cost prohibitive for many physicians to operate clinical laboratories in their offices, manufacturers of laboratory equipment and test kits could seek to increase their sales by marketing point-of-care test equipment to physicians. Diagnostic tests approved or cleared by the FDA for home use are automatically deemed to be “waived” tests under CLIA and may be performed in physician office laboratories with minimal regulatory oversight under CLIA as well as by patients in their homes. Test kit manufacturers could seek to increase sales to both physicians and patients of test kits approved by the FDA for point-of-care testing or home use. Development of such technology and its use by our customers would reduce the demand for our LDT services, including for the MaterniT21 PLUS LDT, and negatively impact our revenues.

***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;
- 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;

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- Sequenom CMM's success in providing its diagnostic testing services, including the MaterniT21 PLUS LDT, and the level of reimbursement and collection obtained for these tests;
- our success in manufacturing, marketing and selling the MassARRAY system;
- 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 system, consumable chips, also known as SpectroCHIP arrays, 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 improved or new LDTs;
- our ability to obtain regulatory clearance or approval of any potential diagnostic product that we develop in the future;
- the level of our legal expenses and any damages or settlement payments arising from ongoing or new patent related litigation; and
- the level of our legal expenses and any fines, damages or settlement payments arising from the lawsuit filed by our former chief financial officer or any future investigation or litigation and the extent to which any of the foregoing is not 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, including the MaterniT21 PLUS LDT, 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 systems would harm our business.***

We expect that sales of MassARRAY systems and consumables will account for most of our total revenues throughout 2012 and perhaps thereafter, unless and until Sequenom CMM's testing services begin to generate significant revenues. The following factors, among others, could affect the demand for MassARRAY systems and services:

- our success in manufacturing, marketing and selling the MassARRAY system;
- our ability to maintain necessary quality standards and specifications for the MassARRAY system;
- 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 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 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 2012 and perhaps thereafter, unless and until our noninvasive prenatal and Sequenom CMM's testing services, including the MaterniT21 PLUS LDT, begin to generate significant revenues, will be derived primarily from MassARRAY systems 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 45% of our total revenues for the

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year ended December 31, 2011, compared to 46% for the year ended December 31, 2010. 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;
- 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 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 fund operations and supply products and services to customers;
- our ability to maintain necessary quality standards and specifications for our SpectroCHIP arrays; or
- our ability to maintain suppliers for components for the MassARRAY system.

***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, has developed, validated and commercialized four LDTs. Sequenom CMM launched its first LDT in 2009 and has 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 Sequenom CMM will have sufficient resources to successfully build, qualify, or operate 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 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

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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, require that laboratories obtain licenses to test specimens from patients residing in those states and additional states may require similar licenses in the future. If Sequenom CMM is unable to obtain and maintain licenses from states where required, it 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.

If Sequenom CMM fails to maintain CLIA requirements, the U.S. Department of Health and Human Services, or HHS, or state agencies could require Sequenom CMM to cease diagnostic testing, including the MaterniT21 PLUS LDT. Even if it were possible for Sequenom CMM to bring its laboratory back into compliance after failure to comply with such requirements, Sequenom CMM could incur significant expenses and potentially lose revenues in doing so. Moreover, new interpretations of current regulations or future changes in regulations under CLIA may make it difficult or impossible for Sequenom CMM to comply with the CLIA classification, which would significantly harm its business.

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

Products that we or our collaborators develop in the molecular 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 PMA 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 under the authority of Section 321(h) of the Federal Food, Drug, and Cosmetic 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.

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In July 2010, the FDA held a two day public meeting to discuss the regulatory oversight of LDTs, which may result in new oversight requirements 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, including the MaterniT21 PLUS LDT, 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 additional 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 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, and have recently published studies of Sequenom CMM's MaterniT21 LDT, and there can be no assurance that such results when published will be viewed favorably by clinicians, patients or investors. For example, a manuscript describing the results from our laboratory verification study was published online in February 2011, in the American Journal of Obstetrics & Gynecology and a manuscript describing Sequenom CMM's validation study of our MaterniT21 LDT was published by our academic collaborators online in October 2011 in Genetics in Medicine. 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.

Performance achieved in published 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 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 or other milestones, as modified, in a timely manner, our and Sequenom CMM's ability to exclusively commercialize these diagnostic tests and LDTs, including the MaterniT21 PLUS LDT, may be adversely affected and could delay or completely terminate our product development and commercialization efforts for these tests.

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***We and our licensees and collaborators may not be successful in developing or commercializing diagnostic products, including noninvasive prenatal diagnostic products, or other products using our equipment, services, or discoveries.***

Development of diagnostic LDTs, including the MaterniT21 PLUS LDT, or other products 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;
- fail to be commercialized prior to the successful marketing of similar products by competitors; or
- be subject to competitive price erosion that makes it uneconomical to market effectively.

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 CUHK) or non-exclusive license rights to intellectual property that are required to commercialize such products. Our agreements may allow our partners significant discretion in electing whether to pursue any of these activities. 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, if patent rights that we rely on are invalidated, or if we 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 by proceedings such as interference, oppositions and reexaminations or in litigation 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,

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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, including the MaterniT21 PLUS LDT. Such adverse decisions may negatively impact our revenues. For example, we were named as a defendant in separate complaints filed by Aria Diagnostics, Inc., Natera, and Verinata Health, Inc. pursuant to which a judicial declaration has been sought that certain of the plaintiffs' activities do not infringe any claim of United States Patent No. 6,258,540. These parties have also sought a judicial declaration that one or more claims of the United States Patent No. 6,258,540 are invalid for failure to comply with the requirements of the patent laws of the United States. 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. The MaterniT21 PLUS LDT uses a sequencing platform 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 sequencing 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 market and commercialize the MaterniT21 PLUS LDT.

Also, in the Veriuata Health Inc. complaint, Verinata Health, Inc. and co-plaintiff Stanford University have alleged our infringement of United States Patent No. 7,888,017 titled "Non-invasive Fetal Genetic Screening by Digital Analysis" and United States Patent No. 8,008,018 titled "Determination of Fetal Aneuploidies by Massively Parallel DNA Sequencing" which include patent claims purportedly covering methods for the noninvasive detection of fetal aneuploidy. Challenging the validity of the '017 and '018 patents and defending against claims of infringement of those patents, or if we are forced to defend against any other asserted intellectual property right, will be costly and divert management's attention and resources. As a result of such disputes, we may have to develop costly alternative 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.

Additionally, on September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The United States Patent Office is currently developing regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act will not become effective until one year or 18 months after its enactment. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

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 market

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and commercialize any of our diagnostic products that are dependent upon such technologies, including the MaterniT21 PLUS LDT. 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 LDTs, including the MaterniT21 PLUS LDT, 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.

***The rights we rely upon to protect the intellectual property underlying our products, including the MaterniT21 PLUS LDT, 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

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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 and Human Services Office of Inspector General, or 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.

In addition to the Anti-Kickback Statute, we are also subject to the physician self-referral laws, commonly referred to as the Stark law, which is a strict liability statute that generally prohibits physicians from referring Medicare patients to providers of “designated health services,” including clinical laboratories, with whom the physician or the physician’s immediate family member has an ownership interest or compensation arrangement, unless an applicable exception applies. Moreover, many states have adopted or are considering adopting similar laws, some of which extend beyond the scope of the Stark law to prohibit the payment or receipt of remuneration for the prohibited referral of patients for designated healthcare services and physician self-referrals, regardless of the source of the payment for the patient’s care. If it is determined that certain of our practices or operations violate the Stark law or similar statutes, we could become subject to civil and criminal penalties, including exclusion from the Medicare programs and loss of government reimbursement. The imposition of any such penalties could harm our 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

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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 systems 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.

Additionally, Sequenom CMM commercialized the MaterniT21 LDT in the fourth quarter of 2011. We may be unable to accurately predict quarterly revenues relating to the MaterniT21 PLUS LDT due to our lack of sales history and our inexperience in marketing and commercializing LDTs.

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 the timing of 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 systems 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

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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 system 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 system. 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 system 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

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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.

***Sequenom CMM depends on third-party products and services for our current and planned LDTs, including the MaterniT21 PLUS LDT.***

Sequenom CMM relies on outside suppliers to provide certain products and the components and materials used for LDTs currently provided as well as LDTs 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 the MaterniT21 PLUS LDT. Also, the MassARRAY 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.

These suppliers may be subject to regulation by the FDA and would therefore need to comply with federal regulations related to the manufacture and distribution of regulated products. Because we cannot ensure the actual production or manufacture of such critical equipment and materials, or the ability of our suppliers to comply with applicable legal and regulatory requirements, we may be subject to significant delays caused by interruption in production or manufacturing.

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 LDTs, which would have an adverse impact on our business, including Sequenom CMM's ability to offer or to continue to offer LDTs. 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 suppliers; and
- Sequenom CMM's inability to provide LDTs, including the MaterniT21 PLUS LDT, 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 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 consents 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 samples, which would hinder our diagnostic product development efforts. We could become involved in legal challenges, which could consume 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

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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 exclusive rights we have acquired related to our development and commercialization of Sequenom CMM's test for risk assessment of developing wet AMD, and other rights we have acquired to potentially expand our product portfolio and generate additional sources of revenue. Disputes may 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.

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 generate any milestone, royalty, or other revenue from sales of these products or applications, including from the MaterniT21 PLUS LDT. 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 or only generate limited 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 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, including the MaterniT21 PLUS LDT, 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

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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, including efforts to market and commercialize the MaterniT21 PLUS LDT. 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; and
- 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

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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; and
- public and private research organizations.

Some of our competitors may have 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. Our announcement in 2009 of the delay in the launch of the trisomy LDT then under development, 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 LDT 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; and
- 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;

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- 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; and
- 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 of 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 LDTs, including the MaterniT21 PLUS LDT, may not be eligible for reimbursement by payors or may become ineligible for reimbursement, which may limit the demand for these tests by physicians and their patients.***

In September 2009, Sequenom CMM commercially launched its testing service for cystic fibrosis carrier screening, in early 2010 it launched its testing service for noninvasive fetal Rhesus D genotyping, in the second quarter of 2011 it launched its AMD test, and in the fourth quarter of 2011 it launched its MaterniT21 LDT, 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.

In the United States, the regulatory process allows diagnostic tests to be marketed regardless of any coverage determinations made by payors. For new diagnostic tests, each third-party payor makes its own decision about which tests it will cover, how much it will pay and whether it will continue reimbursing the test. Clinicians may order diagnostic tests that are not reimbursed by third-party payors if the patient is willing to pay for the test without reimbursement, but coverage determinations and reimbursement levels and conditions are critical to the commercial success of a diagnostic product.

CMS, an agency within the Department of Health and Human Services, establishes reimbursement payment levels and coverage rules for Medicare. CMS currently does not cover the MaterniT21 PLUS LDT. State Medicaid plans and third-party payors establish rates and coverage rules independently. As a result, the coverage determination process is often a time-consuming and costly process that requires us to provide scientific and clinical support for the use of our tests to each payor separately, with no assurance that approval will be obtained. If CMS or other third-party payors decide not to cover our diagnostic tests, including the MaterniT21 PLUS LDT, place significant restrictions on the use of our tests, or offer inadequate payment amounts, our ability to generate revenue from our diagnostic tests could be limited.

Even if one or more third-party payors decides to reimburse for our tests, including the MaterniT21 PLUS LDT, that payor may reduce utilization or stop or lower payment at any time, which could reduce our revenues.

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For example, payment for diagnostic tests furnished to Medicare beneficiaries generally is made based on a fee schedule set by CMS using a statutory formula. In recent years, payments under these fee schedules have decreased and may decrease more. In addition, Medicare fee schedules are impacted by the billing codes selected for reporting services, and changes to certain laboratory billing codes for molecular tests, including our AMD and CF tests, are being considered which may affect payment levels. We cannot predict whether or when third-party payors will cover our tests or offer adequate reimbursement to make them commercially attractive. Clinicians or patients may decide not to order our tests if third-party payments are inadequate, especially if ordering the test could result in financial liability for the patient.

***Billing complexities associated with obtaining payment or reimbursement for our tests may negatively affect our revenues, cash flow and profitability. We may incur additional financial risk related to collections and reimbursement in connection with the commercialization of our molecular diagnostic tests.***

Billing for clinical laboratory testing services is complex. 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. Among the factors complicating our billing of third-party payors are:

- disputes among payors as to which party is responsible for payment;
- disparity in coverage among various payors;
- disparity in information and billing requirements among payors; and
- incorrect or missing billing information, which is required to be provided by the prescribing physician.

These billing complexities, and the related uncertainty in obtaining payment for our tests, could negatively affect our revenues, cash flow and profitability.

***Our failure to comply with governmental payor regulations could result in our being excluded from participation in Medicare, Medicaid or other governmental payor programs, which would decrease our revenues and adversely affect our results of operations and financial condition.***

The Medicare program is administered by CMS, which, like the states that administer their respective state Medicaid programs, imposes extensive and detailed requirements on diagnostic services providers, including, but not limited to, rules that govern how we structure our relationships with physicians, how and when we submit reimbursement claims and how we provide our specialized diagnostic services. Our failure to comply with applicable Medicare, Medicaid and other governmental payor rules could result in our inability to participate in a governmental payor program, our returning funds already paid to us, civil monetary penalties, criminal penalties and/or limitations on the operational function of our laboratory. If we were unable to receive reimbursement under a governmental payor program, a substantial portion of our revenues would be lost, which would adversely affect our results of operations and financial condition.

***We must be in compliance with state and federal security and privacy regulations, which may increase our operational costs.***

The privacy and security regulations under the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (collectively, HIPAA), establish comprehensive federal standards with respect to the uses and disclosures of protected health

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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; and
- administrative, technical and physical safeguards required of entities that use or receive PHI electronically.

As Sequenom CMM launches additional commercial diagnostic tests, it 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. Sequenom CMM has evaluated the security of its computer networks and determined that appropriate measures are in place to safeguard PHI contained on such networks. However, no security system is invulnerable to breach, and unauthorized persons may in the future be able to exploit weaknesses in the security systems of Sequenom CMM's computer networks and gain access to such PHI. Additionally, Sequenom CMM shares PHI with third-party contractors who are contractually obligated to safeguard and maintain the confidentiality of PHI. Unauthorized persons may be able to gain access to PHI stored in such third-party contractors' computer networks. Any wrongful use or disclosure of PHI by Sequenom CMM or its third-party contractors, including disclosure due to data theft or unauthorized access to Sequenom CMM's or its third-party contractors' computer networks, could subject us and Sequenom CMM to fines or penalties that could adversely affect our business and results of operations. 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 by Sequenom CMM or its third-party contractors.

***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 have required the SEC to adopt additional rules and regulations in these areas. 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 and prevent the commercial success of the MaterniT21 LDT.***

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the “PPACA”), which may have far-reaching consequences for most healthcare companies, including diagnostic companies like us. As a result of this new legislation, substantial changes could be made to the current system for paying for healthcare in the United States, including changes made in order to extend medical benefits to those who currently lack insurance coverage.

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.

Extending coverage to a large population could substantially change the structure of the health insurance system and the methodology for reimbursing medical services, drugs and devices. These structural changes could entail modifications to the existing system of third-party payors and government programs, such as Medicare and Medicaid, the creation of a government-sponsored healthcare insurance source, or some combination of both, as well as other changes.

Restructuring the coverage of medical care in the United States could impact the reimbursement for diagnostic tests like ours, including the MaterniT21 PLUS LDT. If reimbursement for our diagnostic tests is substantially less than we or our clinical laboratory customers expect, or rebate obligations associated with them are substantially increased, our business could be materially and adversely impacted. A number of state governors have strenuously opposed certain of the PPACA’s provisions, and initiated lawsuits challenging its constitutionality. These challenges are pending final adjudication in several jurisdictions, including the United States Supreme Court. Congress has also proposed a number of legislative initiatives, including possible repeal of the PPACA. At this time, it remains unclear whether there will be any changes made to the PPACA, whether to certain provisions or its entirety.

Regardless of the impact of PPACA on us, the U.S. government and other governments have shown significant interest in pursuing healthcare reform and reducing healthcare costs. Any government-adopted reform measures could cause significant pressure on the pricing of healthcare products and services, including the MaterniT21 PLUS LDT, in the United States and internationally, as well as the amount of reimbursement available from governmental agencies or other third-party payors. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors to contain or reduce healthcare costs may compromise our ability to set prices at commercially attractive levels for our diagnostic tests, including the MaterniT21 PLUS LDT, and other diagnostic tests that we may develop. Changes in healthcare policy, such as the creation of broad limits for diagnostic products, could substantially diminish the sale of or inhibit the utilization of future diagnostic tests, increase costs, divert management’s attention and adversely affect our ability to generate revenues and achieve consistent profitability.

New laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, relating to healthcare availability, methods of delivery or payment for diagnostic products and services, or sales, marketing or pricing, may also limit our potential revenues, and we may need to revise our research and development or commercialization programs. The pricing and reimbursement environment may change in the future and become more challenging for a number of reasons, including policies advanced by the U.S. government, new healthcare legislation or fiscal challenges faced by government health administration

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authorities. Specifically, in both the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory proposals and initiatives to change the healthcare system in ways that could affect our ability to sell our diagnostic tests, including the MaterniT21 PLUS LDT, profitably. Some of these proposed and implemented reforms could result in reduced utilization or reimbursement rates for our diagnostic products.

***Our business is subject to other complex and sometimes unpredictable government regulations. If we or any of our clinical diagnostic laboratory customers fail to comply with these regulations, we could incur significant fines and penalties.***

As a provider of clinical diagnostic testing products and services, we are subject to extensive and frequently changing federal, state and local laws and regulations governing various aspects of our business. In particular, the clinical laboratory industry is subject to significant governmental certification and licensing regulations, as well as federal and state laws regarding:

- test ordering and billing practices;
- marketing, sales and pricing practices;
- patient privacy, including HIPAA;
- insurance;
- anti-markup legislation; and
- consumer protection.

We are also required to comply with FDA regulation of our manufacturing practices and adverse event reporting activities, and regulation by the FDA of our labeling and promotion activities. In addition, advertising of our tests is subject to regulation by the Federal Trade Commission, or FTC, under the Federal Trade Commission Act, or FTC Act. Violation of any FDA requirement could result in enforcement actions, such as seizures, injunctions, civil penalties and criminal prosecutions, and violation of the FTC Act could result in injunctions and other associated remedies, all of which could have a material adverse effect on our business. Most states also have similar postmarket regulatory and enforcement authority for devices. Additionally, most foreign countries have authorities comparable to the FDA and processes for obtaining marketing approvals. Obtaining and maintaining these approvals, and complying with all laws and regulations, may subject us to similar risks and delays as those we could experience under FDA and FTC regulation. We incur various costs in complying and overseeing compliance with these laws and regulations.

We are unable to predict what additional federal or state legislation or regulatory initiatives may be enacted in the future regarding our business or the healthcare industry in general, or what effect such legislation or regulations may have on us. Federal or state governments may impose additional restrictions or adopt interpretations of existing laws that could have a material adverse effect on us. If we fail to comply with any existing or future regulations, restrictions or interpretations, we could incur significant fines and penalties.

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

We expect that a significant portion of our genetic analysis segment sales will continue to be made outside the United States. Approximately 65% of our genetic analysis segment sales were made outside of the United States during the year ended December 31, 2011, compared to 54% for the year ended December 31, 2010. 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;

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- 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; and
- 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 has laboratory facilities in San Diego, California and Grand Rapids, Michigan. Damage to our facilities due to war, fire, natural disaster, earthquake, 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 that 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, such as the MaterniT21 PLUS LDT, 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. We can provide no assurance that we will be able to avoid significant product liability claims, which could hurt our reputation and our financial condition.

***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 rights, 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 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; and
- securities analysts' earnings projections or recommendations, third-party research recommendations, or general market conditions.

The stock market in general, and The NASDAQ Global Select 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

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Queensland, Australia and Beijing, China. In November 2011 we entered into leases for additional laboratory and office space in San Diego, California and Durham, North Carolina. Collectively, we lease approximately 209,000 square feet under leases that expire at various dates through December 2016, 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**

#### *Patent Litigation*

On December 19, 2011, we were named as a defendant in a complaint filed by plaintiff Aria Diagnostics, Inc. (Aria) in the United States District Court for the Northern District of California. In the complaint, the plaintiff seeks a judicial declaration that no activities related to the plaintiff's non-invasive, prenatal test using cell-free DNA circulating in the blood of a pregnant woman do or will infringe any claim of U.S Patent No. 6,258,540 entitled *Non-Invasive Prenatal Diagnosis* (the '540 Patent), which we have exclusively in-licensed from Isis Innovation Limited (Isis). We intend to vigorously defend against the judicial declaration sought in the complaint. On January 24, 2012, we filed a complaint against defendant Aria in the United States District Court for the Southern District of California (the Aria Complaint). The Aria Complaint also names Isis as a nominal defendant for purposes of subject matter jurisdiction only and it seeks to realign Isis as a plaintiff in the matter. In the Aria Complaint, we have alleged that Aria is directly infringing the '540 Patent. We contend that the complaint filed by Aria is not a proper declaratory judgment action and should be dismissed in favor of the Aria Complaint.

On January 6, 2012, we were named as a defendant in a complaint filed by plaintiff Natera, a Delaware corporation, in the United States District Court for the Northern District of California. In the complaint, the plaintiff seeks a judicial declaration that (i) activities related to the plaintiff's non-invasive, prenatal paternity test do not directly or indirectly infringe any claim of the '540 Patent, which we have exclusively in-licensed from Isis, and (ii) one or more claims of the '540 Patent are invalid for failure to comply with the requirements of the patent laws of the United States. We intend to vigorously defend against the judicial declarations sought in the complaint. On January 24, 2012, we filed a complaint against defendants Natera and DNA Diagnostics Center, Inc. (DDC) in the United States District Court for the Southern District of California (the Natera Complaint). The Natera Complaint also names Isis as a nominal defendant for purposes of subject matter jurisdiction only and it seeks to realign Isis as a plaintiff in the matter. In the Natera Complaint, we have alleged that Natera and DDC are directly infringing the '540 Patent. As was described in our Current Report on Form 8-K filed with the Securities and Exchange Commission on January 11, 2012, Natera filed a complaint in the United States District Court for the Northern District of California seeking a declaratory judgment that it does not infringe the '540 Patent. We contend that the complaint filed by Natera is not a proper declaratory judgment action and should be dismissed in favor of the Natera Complaint.

On February 22, 2012, we and our wholly-owned subsidiary Sequenom Center for Molecular Medicine, LLC (Sequenom CMM) were named as defendants in a complaint filed by plaintiffs Verinata Health, Inc. (Verinata) and The Board of Trustees of the Leland Stanford Junior University (Stanford) in the United States District Court for the Northern District of California. In the complaint (i) Verinata seeks a judicial declaration that activities related to its non-invasive prenatal test using cell-free DNA circulating in the blood of a pregnant

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woman do not directly or indirectly infringe any claim of the '540 Patent, which we have exclusively in-licensed from Isis, (ii) Verinata seeks a judicial declaration that each claim of the '540 Patent is invalid for failure to comply with the requirements of the patent laws of the United States, and (iii) Verinata and Stanford allege that we and Sequenom CMM, by performing its non-invasive prenatal MaterniT21™ laboratory-developed test (LDT), have and continue to directly infringe U.S. Patent No. 8,008,018 entitled *Determination of Fetal Aneuploidies by Massively Parallel DNA Sequencing* and U.S. Patent No. 7,888,017 entitled *Non-invasive Fetal Genetic Screening by Digital Analysis*, each of which have been exclusively licensed to Verinata by Stanford. We intend to vigorously defend against the judicial declarations sought and allegations of infringement set forth in the complaint.

On February 29, 2012, we and our wholly-owned subsidiary Sequenom CMM were named as defendants in a complaint filed by plaintiffs ArcticDx, Inc. (ArcticDx), ArcticAx, Inc. (ArcticAx), and ArcticAx US Ltd. (together with ArcticDx and ArcticAx, collectively referred to as Arctic) in the United States District Court for the Eastern District of Texas. In the complaint (i) ArcticDx alleges that we and Sequenom CMM, by performing its RetnaGene AMD LDT to predict genetic predisposition to late-stage (wet) age-related macular degeneration (AMD), have and continue to directly infringe U.S. Patent No. 8,114,592, which ArcticDx has exclusively licensed from the Cambridge Enterprise Limited, (ii) Arctic seeks a judicial declaration that activities related to its Macula Risk genetic test for the indication of individuals with AMD do not directly or indirectly infringe any claim of U.S. Patent No. 8,053,190 (the '190 Patent), U.S. Patent No. 7,867,727 (the '727 Patent), U.S. Patent No. 7,695,909 (the '909 Patent), U.S. Patent No. 7,351,524 (the '524 Patent), and U.S. Patent No. 8,088,579 (the '579 Patent), all of which we have exclusively in-licensed from Ophtherion, Inc., and (iii) Arctic seeks a judicial declaration that the claims of the '190 Patent, the '727 Patent, the '909 Patent, the '524 Patent, and the '579 Patent are invalid for failure to comply with the requirements of the patent laws of the United States. We intend to vigorously defend against the judicial declarations sought and allegations of infringement set forth in the complaint.

### *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

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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.

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 October 2009, the District Court certified the settlement class in each IPO Case and granted final approval to the settlement. Thereafter, a number of shareholders filed appeals to the Second Circuit, objecting to the settlement. On January 10, 2012, the last of these shareholder appeals was dismissed with prejudice. Accordingly, the settlement is now final, all claims against us and our officers and directors in the IPO Cases will be dismissed 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.

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)

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and plaintiffs filed a single consolidated complaint. A separate federal derivative complaint, *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 had initiated an investigation following our April 2009 announcement regarding the trisomy 21 test then under development. As part of this investigation, the SEC staff 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.

On September 1, 2011, the SEC, pursuant to Section 21C of the Exchange Act, entered a cease-and-desist Order against us relating to our public statements made between June 2008 and January 2009 regarding our trisomy 21 test then under development. In accordance with the cease-and-desist Order, we have agreed not to commit or to cause any future violations of Sections 10(b) and 13(a) of the Exchange Act, and Rules 10b-5, 12b-20, 13a-1, and 13a-11 promulgated thereunder, and monetary penalties were not imposed against us.

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. Prior to sentencing, Dr. Dragon passed away in February 2011.

### *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

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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 have cooperated 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.

*Former Employee 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 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. At this time an estimate cannot reasonably be made regarding the possible loss or range of loss in connection with this matter. The appeal is currently pending.

In addition, from time to time, we may be involved in litigation 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.

**Item 4. MINE SAFETY DISCLOSURES**

Not applicable.

**PART II**

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

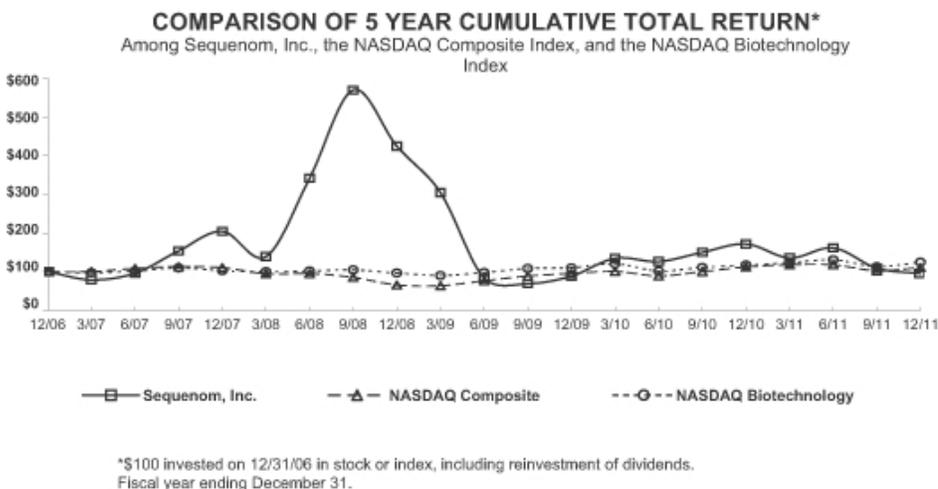
(a) Our common stock is traded on The NASDAQ Global Select Market under the symbol “SQNM.” The following tables set forth the high and low sales prices for the Company’s common stock as reported on The NASDAQ Global Select Market for the periods indicated.

	<u>High</u>	<u>Low</u>
Year Ended December 31, 2011:		
Fourth Quarter	\$5.56	\$ 3.59
Third Quarter	\$ 7.90	\$ 5.10
Second Quarter	\$ 8.54	\$ 6.49
First Quarter	\$ 7.85	\$5.56
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

There were approximately 342 holders of record of our common stock as of March 2, 2012. 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, 2006 and December 31, 2011 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 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.

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**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,				
	2011	2010	2009	2008	2007
(In thousands, except per share data)					
<b>Consolidated statements of operations data</b>					
Revenues:					
Genetic analysis product sales and services	\$ 47,588	\$ 44,905	\$ 37,769	\$ 47,149	\$ 41,002
Diagnostic services	8,319	2,554	94	—	—
Total revenues	55,907	47,459	37,863	47,149	41,002
Cost of revenues:					
Cost of genetic analysis product sales and services	13,283	15,031	14,158	19,590	18,077
Cost of diagnostic services	10,031	3,965	412	—	—
Total cost of revenues	23,314	18,996	14,570	19,590	18,077
Gross margin	32,593	28,463	23,293	27,559	22,925
Operating expenses:					
Research and development	53,585	43,431	37,454	27,455	14,352
Selling and marketing	31,087	28,387	26,845	24,299	17,015
General and administrative	22,185	22,280	28,127	18,436	14,133
Litigation settlement, net	—	55,384	—	—	—
Restructuring	—	—	1,589	—	—
Total operating expenses	106,857	149,482	94,015	70,190	45,500
Loss from operations	(74,264)	(121,019)	(70,722)	(42,631)	(22,575)
Other income (loss), net	202	165	(173)	(1,312)	592
Loss before income taxes	(74,062)	(120,854)	(70,895)	(43,943)	(21,983)
Income tax (expense) benefit	(95)	10	(117)	(211)	—
Net loss	\$ (74,157)	\$ (120,844)	\$ (71,012)	\$ (44,154)	\$ (21,983)
Net loss per share, basic and diluted	\$ (0.75)	\$ (1.69)	\$ (1.16)	\$ (0.83)	\$ (0.57)
Weighted average shares outstanding, basic and diluted	99,143	71,697	61,171	53,129	38,865

	As of December 31,				
	2011	2010	2009	2008	2007
(In thousands)					
<b>Consolidated balance sheet data</b>					
Cash, cash equivalents, marketable securities and restricted cash	\$ 84,282	\$ 136,884	\$ 44,100	\$ 99,700	\$ 52,150
Working capital	74,512	132,320	45,473	103,246	52,690
Total assets	135,547	174,279	86,645	140,484	76,046
Total long-term obligations	14,375	3,562	5,226	4,779	5,744
Total stockholders’ equity	91,388	150,732	63,658	116,213	54,265

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

**Overview**

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, and other medical conditions such as oncology, infectious diseases and autoimmunity.

Our proprietary MassARRAY system is comprised of hardware, software applications, and 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, bioagriculture, biotechnology 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 employees serving North America, Europe and Asia, in addition to utilizing sales and distribution partners in several major countries throughout the world.

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, and other medical conditions such as oncology, infectious diseases and autoimmunity. Currently, we are primarily focused on developing and commercializing prenatal diagnostic tests using our foundational, patent-protected, noninvasive, circulating cell-free fetal, or cff, nucleic acid-based assay technology, which we in-license from Isis Innovation Limited, or Isis. This technology uses a maternal blood sample for a prenatal diagnosis or risk assessment in order to provide reliable information about the presence, amount, or absence of fetal genetic material in early pregnancy. We have branded our technology for prenatal diagnostics under the trademark SEQuEDx. 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 execute 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 in the United States of certain of our *in vitro* diagnostic tests where we believe it will afford us competitive advantages to do so, such as providing us with the flexibility to sell the test as an FDA cleared IVD kit to other laboratories, and an alternative in the event the FDA decides to exercise its enforcement jurisdictional authority with respect to regulation of laboratory-developed tests, or LDTs, as *in vitro* diagnostics. Historically, the FDA has exercised enforcement discretion and exempted from regulation LDTs, but the FDA has stated that additional regulation of LDTs may be warranted. In 2010 we submitted a pre-investigational device exemption submission and supplements 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 designs. We have invested substantially in Sequenom Center for Molecular Medicine, LLC, or Sequenom CMM's information technology infrastructure to enhance the capabilities of the laboratories to track samples and provide electronic ordering and reporting and have put in place sample collection and transportation logistics that can be scaled as demand for Sequenom CMM's molecular diagnostic testing services increases. Currently, we offer pricing on our diagnostic tests that address the following general parameters: Insured patients have established maximum out-of-pocket costs with the payor being billed at the full list price and any outstanding amounts due are pursued from the payor, not the patient, on appeal. Uninsured patients are billed using a separately maintained price list. Due to our current out-of-network provider status associated with the lack of existing contracts with payors and the current level of adoption rates in particular with our LDTs for age-related macular degeneration, or AMD, and MaterniT21 PLUS, we expect billed amounts will fluctuate until these factors are resolved. Sequenom CMM intends to provide reimbursement recommendations and enter into contracts with third-party payors to establish contractual pricing for its LDTs.

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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 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 potential clinical utility in diagnosis, prognosis and monitoring of diseases.

We have targeted customers conducting quality genotyping, 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, 2011, 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 AMD and trisomy 21 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 of all LDTs 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 \$792.3 million as of December 31, 2011, 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, 2011, we had available cash and cash equivalents and current marketable securities totaling \$84.2 million and working capital of \$74.5 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

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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 1 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***

Our revenue is generated primarily from the sale of products and services. Genetic analysis product sales and services revenue primarily consists of sales of system instrumentation and consumables used in genetic analysis, including extended warranty services associated with the instrumentation as well as other amounts earned under contract research agreements. Diagnostic services revenues consist of performing LDTs for cystic fibrosis, or CF, carrier screening, fetal Rhesus D, or RHD, genotyping, AMD, and MaterniT21 PLUS.

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. 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.

In October 2009, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2009-13, *Multiple-Deliverable Revenue Arrangements*. The new standard changes the requirements for establishing separate units of accounting in a multiple element arrangement and requires the allocation of arrangement consideration to each deliverable to be based on the relative selling price. We adopted the standard and, effective as of January 1, 2011, when a sales arrangement contains multiple elements, such as hardware and software products, licenses and/or services, we allocate revenue to each element based on a selling price hierarchy. The selling price for a deliverable is based on its vendor specific objective evidence, or VSOE, if available, third-party evidence, or TPE, if VSOE is not available, or estimated selling price, if neither VSOE nor TPE is available. We limit the amount of revenue recognition for delivered elements to the amount that is not contingent on the future delivery of products or services, future performance obligations, or subject to customer-specified return or refund privileges.

We evaluate deliverables in a multiple-element arrangement to determine whether each represents a separate unit of accounting. A deliverable constitutes a separate unit of accounting when it has standalone value to the customer and there are no customer-negotiated refund or return rights for the delivered elements. Items are considered to have standalone value when they are sold separately by any vendor or when the customer could sell the item on a standalone basis. In instances when the aforementioned criteria are not met, the deliverable is combined with the undelivered elements and the allocation of the arrangement consideration and revenue recognition is determined for the combined unit as a single unit. Allocation of the consideration is determined by management at the arrangement inception on the basis of each unit's relative selling price.

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We establish VSOE of selling price using the price charged for a deliverable when sold separately and, in rare instances, using the price established by management having the relevant authority. In order to establish VSOE of selling price, we must regularly sell the product or service on a stand-alone basis with a substantial majority priced within a relatively narrow range. VSOE of selling price is usually the midpoint of that range. If there are not a sufficient number of standalone sales and VSOE of selling price cannot be determined, then we consider whether third party evidence can be used to establish selling price. Due to the lack of similar products and services sold by other companies within the industry, we have not established selling price using third-party evidence. If neither VSOE nor third party evidence of selling price exists, we determine our best estimate of selling price. TPE of selling price is established by evaluating largely similar and interchangeable competitor products or services in standalone sales to similarly situated customers. The best estimate of selling price is established considering internal factors such as historical selling prices, pricing practices and controls, and customer segment pricing strategies.

Diagnostic revenues from Sequenom CMM have been recognized on a cash basis due to the lack of contractual reimbursement 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. Insured patients have established maximum out-of-pocket costs with the payor being billed at the full list price and any outstanding amounts due are pursued from the payor, not the patient, on appeal. 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. We will continue to recognize revenue upon cash collection until we can reliably estimate the amount that will be ultimately collected.

### ***Accounts Receivable***

We invoice our genetic analysis product sales and services as orders are shipped and any other contractual obligations are met. Our contracts typically require payment within 30 to 60 days of the date of invoice. We maintain allowances for doubtful accounts for estimated losses resulting from the inability of our clients to make required payments. We specifically analyze accounts receivable and historical bad debts, client credit, current economic trends, and changes in client payment trends when evaluating the adequacy of the allowance for doubtful accounts. Account balances are charged-off against the allowance when it is probable the receivable will not be recovered.

We bill third-party payors for our LDTs upon providing test results to ordering physicians. As such, we take assignment of benefits and the risk of collection with third-party payors and we continue to monitor the collection history for third-party payors. We do not record accounts receivable for billings to third-party payors as these revenues are recognized on a cash basis.

We cannot guarantee that we will continue to experience the same credit loss rates that we have in the past. Measurement of such losses requires consideration of historical loss experience, including the need to adjust for current conditions, and judgments about the probable effects of relevant observable data, including present economic conditions such as delinquency rates and financial health of specific customers. We consider all available information in our assessments of the adequacy of the reserves for uncollectible accounts. For billings directly to physician offices or to uninsured patients, we continue to recognize revenue on a cash basis.

### *Use of Estimates*

The preparation of financial statements in conformity with generally accepted accounting principles, or GAAP, 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. 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 2011, 2010, or 2009.

- *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, including expiration. 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, 2011, 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.* We are required to measure and recognize compensation expense for all share-based payments made to employees and directors based on estimated fair value, net of an estimated forfeiture rate. We estimate the fair value of stock options granted and stock purchases under our employee stock purchase plan using the Black-Scholes-Merton (BSM) option-pricing model. The fair value of our restricted stock units is based on the market price of our common stock on the date of grant. The determination of fair value of share-based awards using the BSM model requires the use of certain estimates and highly judgmental assumptions that affect the amount of share-based compensation expense recognized in our consolidated statements of income. These include estimates of the expected volatility of our stock price, expected life of an award, expected dividends, and the risk-free interest rate. We amortize the fair value of share-based compensation on a straight-line basis over the requisite service periods of the awards. If any of the assumptions used in the BSM model change significantly, share-based compensation expense may differ materially from what we have recorded in the current period.

### ***Recent Accounting Pronouncements***

In September 2011, the FASB issued an ASU related to Testing Goodwill for Impairment that gives companies the option to first perform a qualitative assessment to determine whether it is more likely than not (a likelihood of more than 50%) that the fair value of a reporting unit is less than its carrying amount. Under this guidance, only if we conclude that it is more likely than not that the fair value of a reporting unit is less than its carrying amount are we required to perform the two-step test. Otherwise, we can skip the two-step test. This guidance is effective for fiscal years beginning after December 15, 2011 with early adoption permitted. We have early adopted this guidance and performed the qualitative assessment during our annual goodwill impairment assessment.

In April 2010, the FASB issued an 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 was effective for us beginning January 1, 2011. The adoption of this update did not have a material impact on our consolidated financial statements. We do not expect to receive any significant milestone revenue from our current license and collaboration agreements.

In January 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 was effective for us beginning January 1, 2011. The adoption of this update did not have a material impact on our consolidated financial statements.

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In October 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 was effective for us beginning January 1, 2011. The adoption of this update did not have a material impact on our consolidated financial statements.

#### *New Accounting Standards Not Yet Adopted*

In June 2011, the FASB issued an ASU related to the Presentation of Comprehensive Income. The guidance requires an entity to present items of net income and other comprehensive income, or OCI, and total comprehensive income either in a single continuous statement of comprehensive income or two separate but continuous statements. We will no longer be allowed to present OCI in the statement of stockholders' equity. Earnings per share would continue to be based on net income. Although existing guidance related to items that must be presented in OCI has not changed, companies will be required to display reclassification adjustments for each component of OCI in both net income and OCI. Also, companies will need to present the components of other comprehensive income in their interim and annual financial statements. This guidance is required to be implemented retrospectively during interim and annual periods beginning after December 15, 2011, which will be our fiscal year 2012. The adoption of this update is not expected to have a material impact on our consolidated financial statements.

In May 2011, the FASB issued an ASU related to Fair Value Measurements and Disclosures that clarified and amended the wording used to describe many of the requirements in GAAP for measuring fair value and for disclosing information about fair value measurements. The FASB also clarified the intent of existing fair value measurement requirements. The new and revised disclosures are required to be implemented prospectively during interim and annual periods beginning after December 15, 2011, which will be our fiscal year 2012. Early application is not permitted. The adoption of this update is not expected to have a material impact on our consolidated financial statements.

### Results of Operations

#### Years ended December 31, 2011 and 2010

##### *Revenues*

Genetic analysis product sales and services revenues were derived from sales of consumables, including our SpectroCHIP arrays used with our iPLEX and other assays, MassARRAY systems, maintenance agreements, sales and licensing of our proprietary software, and contract research services. Diagnostic revenues were primarily from the sale of Sequenom CMM's CF and RHD LDTs. Collections from the sale of Sequenom CMM's AMD and MaterniT21 LDTs were not significant for the periods presented due to commencement of their commercialization in the second and fourth quarters of 2011, respectively.

	Years Ended December 31,		\$	%
	2011	2010	Change	Change
Genetic analysis product sales and services (in thousands)	\$ 47,588	\$ 44,905	\$ 2,683	6%
Diagnostic services (in thousands)	8,319	2,554	5,765	226%
Total revenues	<u>\$55,907</u>	<u>\$47,459</u>	<u>\$ 8,448</u>	<u>18%</u>

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The increase in our genetic analysis product sales and services revenues is primarily attributable to our larger installed base of MassARRAY systems against the comparative period, which resulted in increased consumables orders from our customers in the translational research and agricultural biology markets against the comparative period which resulted in an increase of consumables revenues to \$24.9 million from \$22.0 million during the years ended December 31, 2011 and 2010, respectively. Contract research services increased to \$2.6 million from \$2.5 million during the years ended December 31, 2011 and 2010, respectively. These increases were partially offset by a decrease in system sales to \$14.8 million from \$15.4 million primarily due to a decrease in the number of MassARRAY systems sold during the current period as compared to the same period in 2010.

Diagnostic services revenue is recognized upon cash collection as payments are received. The increase in our diagnostic revenue is attributable to an increase in the number of tests performed during the year ended December 31, 2011, compared to the same period in 2010.

Domestic and non-U.S. revenues were \$27.0 million and \$28.9 million for the year ended December 31, 2011, respectively, and \$21.9 million and \$25.6 million for the year ended December 31, 2010, respectively.

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, revenue recognition criteria, the overall acceptance and demand for our new and existing commercial products and services, as well as the adoption rates of our MaterniT21 PLUS LDT, cystic fibrosis carrier screening, Rhesus D genotyping, and AMD tests, as well as future tests.

### ***Cost of Genetic Analysis Product Sales and Services and Diagnostic Services Revenues and Gross Margins***

Gross margin consists of our revenues less cost of revenues. Cost of revenues consists of employee-related costs (salaries, bonuses, fringe benefits, and stock-based compensation) of our laboratory and manufacturing personnel, and other support personnel, as well as outside laboratory costs, laboratory and manufacturing supplies, logistic costs, depreciation, and administrative-related costs allocated to cost of revenues.

	Years Ended December 31,		\$ Change	% Change
	2011	2010		
Gross margin ( <i>in thousands</i> )	\$32,593	\$28,463	\$4,130	15%
Gross margin ( <i>% of revenues</i> )	58%	60%		

Cost of genetic analysis product sales and services for the years ended December 31, 2011 and 2010 were \$13.3 million and \$15.0 million, respectively. Gross margin as a percentage of genetic analysis product sales and services revenues for the year ended December 31, 2011 was 72%, compared to 67% for the same period in 2010. The increase is due to product mix, including increased consumables, which typically have higher margins, as well as higher gross margin on systems sales related to a higher average selling price and a decrease in low margin spare parts replacements.

Costs of diagnostic services revenues are recognized upon providing test results to ordering physicians and were \$10.0 million and \$4.0 million for the years ended December 31, 2011 and 2010, respectively. Gross margin as a percentage of diagnostic services revenues was negative for the years ended December 31, 2011 and 2010. Due to revenue being recognized when cash is received, costs incurred in one period may relate to revenue recognized in a later period. Gross margin on diagnostic tests were affected by test volumes, cash collected during the period, overall reimbursement for the amount paid per test, and laboratory operational costs.

We believe that gross margin in future periods will fluctuate on a quarterly basis and be affected by, among other things, the selling price for systems and consumables, consumable sales per MassARRAY system sold, the mix of product sales and the type of services, competitive conditions, sales volumes, discounts offered, sales

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through 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 our diagnostic tests, the levels of reimbursement, and payor and other contracts we may enter into for our tests.

**Research and development expenses**

Research and development expenses consisted primarily of salaries and related personnel expenses, product development costs, quality and regulatory costs, and expenses relating to licensing costs and work performed under research contracts.

	Years Ended December 31,		\$ Change	% Change
	2011	2010		
Research and development ( <i>in thousands</i> )	\$53,585	\$43,431	\$10,154	23%
Research and development ( <i>% of revenues</i> )	9.6%	9.2%		

The increase in research and development expenses for the year ended December 31, 2011, as compared to the same period in 2010 is primarily related to higher labor costs, including bonuses and stock-based compensation, of \$5.2 million associated with the expansion of Sequenom CMM's CLIA laboratory, higher Sequenom CMM's CLIA laboratory supply expenses of \$3.8 million related to the expansion of the laboratory, higher research-related intellectual property licensing and collaboration costs of \$3.2 million, higher overhead and depreciation expenses of \$1.2 million related to increased capital acquisitions, higher consulting costs of \$0.8 million associated with our completion of the MaterniT21 LDT validation, and \$0.1 million of higher travel costs related to our increase in operations; partially offset by lower clinical expenses of \$4.1 million related to the completion of major trisomy 21 development studies.

**Selling and marketing expenses**

Selling and marketing expenses consisted primarily of salaries and related expenses for sales and marketing, customer support, and business development personnel and their related department expenses.

	Years Ended December 31,		\$ Change	% Change
	2011	2010		
Selling and marketing ( <i>in thousands</i> )	\$31,087	\$28,387	\$2,700	10%
Selling and marketing ( <i>% of revenues</i> )	5.6%	6.0%		

The increase in selling and marketing expenses for the year ended December 31, 2011 compared to the same period in 2010 is primarily related to higher labor costs, including bonuses and stock-based compensation, of \$2.8 million associated with the expansion of Sequenom CMM's CLIA laboratory, higher travel and marketing expense of \$1.1 million associated with the increase of our sales force and support of the MaterniT21 LDT launch, and higher shipping costs of \$0.4 million related to the increase in diagnostic test volumes; partially offset by lower bad debt expense of \$0.9 million as compared to the prior year and lower consulting costs of \$0.6 million related to the elimination of a third-party sales force in 2010.

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[Table of Contents](#)**General and administrative expenses**

General and administrative expenses consisted primarily of salaries and related expenses for executive, legal, finance, information technology, and human resource personnel, and their related department expenses.

	Years Ended December 31,		\$ Change	% Change
	2011	2010		
General and administrative ( <i>in thousands</i> )	\$22,185	\$22,280	\$(95)	0%
General and administrative ( <i>% of revenues</i> )	40%	47%		

The decrease in general and administrative expenses for the year ended December 31, 2011 from the same period in 2010 was primarily due to lower legal costs of \$2.3 million associated with decreased investigative and SEC-related activities, lower overhead, depreciation, and facilities expenses of \$0.7 million, and lower third-party marketing costs of \$0.3 million related to non-recurring market research performed in 2010; partially offset by higher labor costs, including bonuses and stock-based compensation, of \$2.3 million associated with increased headcount, higher consulting expenses of \$0.5 million associated with our use of third-party billing providers, and higher audit and tax fees of \$0.4 million associated with our increase in operations.

**Litigation Settlement**

Litigation settlement expense, net was \$0 and \$55.4 million for the years ended December 31, 2011 and 2010, respectively.

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' counsel in August 2010 and the revaluation to fair value for the remaining shares that were issued to the members of the 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.

**Interest Income**

Interest income was \$71,000 and \$162,000 for the years ended December 31, 2011 and 2010, 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 2011, as compared to the same period in 2010.

**Gain (Loss) on Marketable Securities**

Gain on marketable securities was \$42,000 and \$111,000 for the years ended December 31, 2011 and 2010, respectively. The decrease is due to a net realizable loss attributable to fluctuations in the market.

### **Interest Expense**

Interest expense was \$366,000 and \$190,000 for the years ended December 31, 2011 and 2010, respectively. The increase was attributable to new debt obligations entered into during 2011.

### **Other Income, net**

Other income, net, was \$455,000 and \$82,000 for the years ended December 31, 2011 and 2010, respectively. The increase was due to the receipt in 2011 of a research and development grant from the U.S. government of approximately \$244,000, plus approximately \$129,000 in landlord reimbursements related to property loss and other miscellaneous income.

### **Income Tax Expense**

We had an income tax expense of \$95,000 and a benefit of \$10,000 for the years ended December 31, 2011 and 2010, respectively. Income tax expense and benefit in both periods was primarily due to statutory tax liabilities resulting from our foreign operations.

## **Years ended December 31, 2010 and 2009**

### **Revenues**

Genetic analysis product sales and services revenues were derived from sales of consumables, including our SpectroCHIP arrays used with our iPLEX and other assays, MassARRAY systems, maintenance agreements, sales and licensing of our proprietary software, and contract research services. Diagnostic revenues were primarily from the sale of Sequenom CMM's CF and RHD LDTs.

	Years Ended December 31,		\$ Change	% Change
	2010	2009		
Genetic analysis product sales and services (in thousands)	\$ 44,905	\$ 37,769	\$ 7,136	19%
Diagnostic services (in thousands)	2,554	94	2,460	2,617%
Total revenues	\$47,459	\$ 37,863	\$9,596	25%

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.

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Diagnostic services revenue was recognized upon cash collection as payments are received. The increase in our diagnostic services revenues was attributable to an increase in the number of tests performed during the year ended December 31, 2010, compared to the same period in 2009.

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 on our expenditure on grant research and the receipt of the grant funding from the sponsoring agencies.

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.

#### ***Cost of Genetic Analysis Product Sales and Services and Diagnostic Services Revenues and Gross Margins***

Gross margin consists of our revenues less cost of revenues. Cost of revenues consists of employee-related costs (salaries, bonuses, fringe benefits, and stock-based compensation) of our laboratory and manufacturing personnel, and other support personnel, as well as outside laboratory costs, laboratory and manufacturing supplies, logistic costs, depreciation, and administrative-related costs allocated to cost of revenues.

	Years Ended December 31,		\$ Change	% Change
	2010	2009		
Gross margin ( <i>in thousands</i> )	\$28,463	\$23,293	\$5,170	22%
Gross margin ( <i>% of revenues</i> )	60%	62%		

Cost of genetic analysis product sales and services for the years ended December 31, 2010 and 2009 was \$15.0 million and \$14.2 million, respectively. Gross margins on genetic analysis product sales and services for the year ended December 31, 2010 were 67%, compared to 63% for the same period in 2009. The increase was due to an increase in consumables sales, which historically sell at higher average gross margins and an increase in research services with a high gross margin.

Costs of diagnostic services revenues are recognized at the completion of testing and were \$4.0 million and \$0.4 million for the years ended December 31, 2010 and 2009, respectively. Gross margins were negative for the years ended December 31, 2010 and 2009, respectively, as we built test volume to cover costs associated with running our diagnostic tests and other capacity related expenses. Due to revenue being recognized when cash is received, costs incurred in one period may relate to revenue recognized in a later period. Gross margin on diagnostic tests were affected by test volumes, cash collected during the period, overall reimbursement for the amount paid per test, and favorable laboratory operational costs.

#### ***Research and development expenses***

Research and development expenses consisted primarily of salaries and related personnel expenses, product development costs, quality and regulatory costs, and expenses relating to work performed under research contracts.

	Years Ended December 31,		\$ Change	% Change
	2010	2009		
Research and development ( <i>in thousands</i> )	\$43,431	\$37,454	\$5,977	16%
Research and development ( <i>% of revenues</i> )	92%	99%		

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

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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.

### ***Selling and marketing expenses***

Selling and marketing expenses consisted primarily of salaries and related expenses for sales and marketing, customer support, and business development personnel and their related department expenses.

	Years Ended December 31,		\$ Change	% Change
	2010	2009		
Selling and marketing ( <i>in thousands</i> )	\$28,387	\$26,845	\$1,542	6%
Selling and marketing ( <i>% of revenues</i> )	60%	71%		

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.

### ***General and administrative expenses***

General and administrative expenses consisted primarily of salaries and related expenses for executive, legal, finance, information technology, and human resource personnel, and their related department expenses.

	Years Ended December 31,		\$ Change	% Change
	2010	2009		
General and administrative ( <i>in thousands</i> )	\$22,280	\$28,127	\$(5,847)	-21%
General and administrative ( <i>% of revenues</i> )	47%	74%		

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.

### ***Litigation Settlement***

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' counsel in August 2010 and the revaluation to fair value for the remaining shares that were issued to the members of the 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.

### **Liquidity and Capital Resources**

As of December 31, 2011, cash, cash equivalents and current marketable securities totaled \$84.2 million, compared to \$135.5 million at December 31, 2010. 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.

We have a history of recurring losses from operations and had an accumulated deficit of \$792.3 million as of December 31, 2011. Our capital requirements to sustain operations, including research and development projects, have been and will continue to be significant. As of December 31, 2011 and 2010, we had working capital of \$74.5 million and \$132.3 million, respectively.

On January 25, 2012, we completed an underwritten public offering of 14,950,000 shares of our common stock, including 1,950,000 shares sold pursuant to the full exercise of an over-allotment option previously granted to the underwriters. All of the shares were offered by us at a price of \$4.15 per share. The gross proceeds to us from this offering were approximately \$62.0 million, before deducting the underwriting discounts and commissions and other estimated offering expenses payable by us.

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, 2011 was \$51.3 million, compared to \$42.6 million and \$48.7 million for the years ended December 31, 2010 and 2009, respectively. Our use of cash was primarily a result of the net loss of \$74.2 million for the year ended December 31, 2011, adjusted for non-cash items related stock-based compensation of \$12.1 million, depreciation and amortization of \$7.1 million, warrants issued for license of \$1.2 million, and deferred license expense of \$1.5 million, which were offset by other non-cash items totaling \$0.7 million. The changes in our operating assets and liabilities consisted of higher inventory and accounts receivable balances, plus higher prepaid and other asset balances that resulted in a cash usage of \$4.9 million; partially offset by higher accounts payable and other liabilities that resulted in a cash provision of \$6.7 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 \$35.1 million, consisted of purchases for capital equipment, leasehold improvements, and intangible assets that used \$16.2 million in cash during the year ended December 31, 2011, compared to \$4.9 million and \$8.7 million for the same periods in 2010 and 2009, respectively.

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Net cash provided by financing activities was \$15.0 million during the year ended December 31, 2011, compared to \$140.3 million and \$0.2 million in 2010 and 2009, respectively. Financing activities during the year ended December 31, 2011, included proceeds from drawing on our term loan of \$15.0 million, \$1.8 million from the exercise of stock options and employee contributions under our employee stock purchase plan, offset by \$1.8 million in payments on our long-term debt and capital lease obligation.

The following table summarized our contractual obligations as of December 31, 2011 (in thousands):

<u>Contractual obligations</u>	<u>Total</u>	<u>Less Than 1 Year</u>	<u>1-3 Years</u>	<u>3-5 Years</u>	<u>After 5 Years</u>
Purchase obligations	\$ 11,233	\$ 11,228	\$ 5	\$ —	\$ —
Long-term debt	15,175	1,902	10,995	2,278	—
Collaborations	19,040	1,905	4,390	3,625	9,120
Operating leases	28,126	7,465	14,142	6,519	—
Total contractual obligations	<u>\$ 73,574</u>	<u>\$ 22,500</u>	<u>\$ 29,532</u>	<u>\$ 12,422</u>	<u>\$ 9,120</u>

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. 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.

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

### **Marketable Securities and Fair Value Measurements**

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 this level, we research the reasons for the fall and determine if we should continue to hold the investment in order to minimize our exposure to 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, 2011 and 2010, 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.

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**Foreign currency rate fluctuations**

We have foreign operations whose functional currencies are the Great British Pound (GBP), the Japanese Yen (Yen), and the Euro (EUR). The subsidiaries' accounts are translated from the relevant functional currency to the United States Dollar (USD) 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 USD.

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.

<u>Functional currency of operations</u>	As of December 31, 2011	
	Net foreign monetary assets/(liabilities)	
	AUD	EUR
USD	\$676,000	\$408,000

A movement of 10% in the USD to AUD exchange rate would create an unrealized gain or loss of approximately \$68,000. A movement of 10% in the USD dollar to EUR exchange rate would create an unrealized gain or loss of approximately \$41,000. We do not believe that a movement in the exchange rate between the USD and the GBP, the Yen, or any other foreign currencies, to which we are exposed, respectively, would have a material impact on our business or operating results during the periods presented.

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, 2011. We had no deferred gains or losses during the years ended December 31, 2011, 2010, or 2009.

**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**

The financial statements and supplemental data required by this item are set forth at the pages indicated in Part IV, Item 15(a)(1) of this annual report.

**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 rules and forms of the Securities and Exchange Commission's, or SEC, and that such information is accumulated and communicated to our management, including our Chief Executive Officer, or CEO, who is our principal executive officer, and Chief Financial Officer, or CFO, who is our principal financial and accounting officer, as appropriate, to allow timely decisions regarding required disclosure.

Our disclosure controls and procedures have been designed to provide reasonable assurance that we record, process, summarize, and report information we are required to disclose in our periodic reports filed with the SEC in the manner and within the time periods specified in the SEC's rules and forms. Our disclosure controls and procedures are also designed to provide reasonable assurance that the information is accumulated and communicated to our management, including our CEO and CFO, 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 CEO and CFO, 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 CEO and CFO concluded that our disclosure controls and procedures were effective as of December 31, 2011 and were operating to provide reasonable assurance 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 CEO and CFO, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Our management does not expect that our 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, as such item is defined in Exchange Act Rules 13a-15(f), refers to the process designed by, or under the supervision of, our CEO and CFO, 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;

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(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, 2011. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis. In our assessment of the effectiveness of internal control over financial reporting as of December 31, 2011, we identified a material weakness in internal controls over the validation of underlying data used to support the diagnostic revenue accrual process. Our processes, procedures and controls related to diagnostic revenue reporting were not effective to ensure that the underlying data could be relied upon to analyze the collectability of diagnostic revenue to record such revenues on an accrual basis in accordance with U.S. GAAP and there was a reasonable possibility that a material misstatement would not be prevented or detected in the consolidated financial statements. Accordingly, we continue to recognize diagnostic revenues on a cash basis due to the lack of contractual reimbursement agreements with third-party payors and limited collections experience. Therefore, by recording diagnostic revenues on a cash basis, management has concluded that the material weakness has been remediated.

The effectiveness of our internal control over financial reporting as of December 31, 2011 has been audited by Ernst & Young LLP, an independent registered public accounting firm, and, based on that audit, issued an adverse opinion as stated in their report 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, except as discussed above, 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, 2011, 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.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weakness has been identified and included in management's assessment. The Company did not have internal controls over the validation of underlying data used to support the diagnostic revenue accrual process. 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, 2011 and 2010, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2011. This material weakness was considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2011 consolidated financial statements, and this report does not affect our report dated March 9, 2012, which expressed an unqualified opinion on those financial statements.

In our opinion, because of the effect of the material weakness described above on the achievement of the objectives of the control criteria, Sequenom, Inc. has not maintained effective internal control over financial reporting as of December 31, 2011, based on the COSO criteria.

/s/ Ernst & Young LLP

San Diego, California  
March 9, 2012

**Item 9B. OTHER INFORMATION**

None

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## 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 required by this item are submitted in a separate section beginning on page F-1 of this annual report.

(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.

<u>Exhibit Number</u>	<u>Description of Document</u>
3.1 <sup>(1)</sup>	Restated Certificate of Incorporation of the Registrant.
3.2 <sup>(2)</sup>	Restated bylaws of Registrant, as amended.
3.3 <sup>(3)</sup>	Registrant's Certificate of Designation of Series A Junior Participating Preferred Stock.
4.1 <sup>(1)</sup>	Specimen common stock certificate.
4.2 <sup>(3)</sup>	Rights Agreement dated as of March 3, 2009, between the Registrant and American Stock Transfer and Trust Company, LLC.
4.3 <sup>(3)</sup>	Form of Right Certificate.
4.4 <sup>(29)</sup>	Warrant dated May 3, 2011, issued to the Chinese University of Hong Kong Foundation Limited.
10.1 <sup>(4)</sup>	Form of Warrant Agreement between the Registrant and holders of the Series C Preferred Stock warrants.
10.2 <sup>(1)</sup>	Form of Indemnification Agreement between the Registrant and each of its officers and directors.
10.3 <sup>(4)#</sup>	1994 Stock Plan.
10.4 <sup>(4)#</sup>	1994 Stock Plan Form of Non-Qualified Stock Option Grant.
10.5 <sup>(4)#</sup>	1994 Stock Plan Form of Incentive Stock Option Grant.
10.6 <sup>(4)#</sup>	1994 Stock Plan Form of Stock Restriction Agreement.
10.7 <sup>(4)#</sup>	1998 Stock Option/Stock Issuance Plan.
10.8 <sup>(4)#</sup>	1998 Stock Option/Stock Issuance Plan Form of Notice of Grant of Stock Option.
10.9 <sup>(4)#</sup>	1998 Stock Option/Stock Issuance Plan Form of Stock Option Agreement.
10.10 <sup>(4)#</sup>	1998 Stock Option/Stock Issuance Plan Form of Stock Purchase Agreement.
10.11 <sup>(4)#</sup>	1998 Stock Option/Stock Issuance Plan Form of Stock Issuance Agreement.
10.12 <sup>(5)#</sup>	1999 Stock Incentive Plan, as amended.
10.13 <sup>(4)#</sup>	1999 Stock Incentive Plan Form of Notice of Grant of Stock Option.
10.14 <sup>(4)#</sup>	1999 Stock Incentive Plan Form of Stock Option Agreement.

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<u>Exhibit Number</u>	<u>Description of Document</u>
10.15 <sup>(6)</sup> #	1999 Employee Stock Purchase Plan, as amended.
10.16 <sup>(7)</sup> #	2006 Equity Incentive Plan, as amended.
10.17 <sup>(1)</sup> #	2006 Equity Incentive Plan Form of Stock Option Grant Notice.
10.18 <sup>(1)</sup> #	2006 Equity Incentive Plan Form of Stock Option Agreement.
10.19 <sup>(8)</sup> #	2006 Equity Incentive Plan Form of Notice of Exercise.
10.20 <sup>(9)</sup> #	2006 Equity Incentive Plan Form of Restricted Stock Unit Award Grant Notice.
10.21 <sup>(9)</sup> #	2006 Equity Incentive Plan Form of Restricted Stock Unit Award Agreement.
10.22 <sup>(10)</sup>	Business Loan Agreement, dated March 3, 2000, between the Registrant and Union Bank of California.
10.23 <sup>(11)</sup>	Building Lease Agreement, dated March 29, 2000, between the Registrant and TPSC IV LLC.
10.24 <sup>(12)</sup> #	Form of Medical Expense Reimbursement Exec-U-Care Plan.
10.25 <sup>(13)</sup> #	Form of Stock Issuance Agreement under 1999 Stock Incentive Plan.
10.26 <sup>(14)</sup>	Amendment Number One to Lease dated March 29, 2000, by and between the Registrant and TPSC IV LLC dated September 9, 2005.
10.27 <sup>(14)</sup>	Common Stock Warrant, dated September 9, 2005, issued to Kwacker, Ltd.
10.28 <sup>(15)</sup> *	Exclusive License of Technology Agreement, dated October 14, 2005, by and between the Registrant and ISIS Innovation Limited.
10.29 <sup>(16)</sup>	Form of Warrant issued pursuant to the Amended and Restated Securities Purchase Agreement dated March 30, 2006.
10.30 <sup>(17)</sup> *	Amendment to Exclusive License of Technology Agreement dated October 19, 2006, by and between the Registrant and ISIS Innovation Limited.
10.31 <sup>(18)</sup> #	Form of Restricted Stock Bonus Grant Notice under 2006 Equity Incentive Plan.
10.32 <sup>(18)</sup> #	Form of Restricted Stock Bonus Agreement under 2006 Equity Incentive Plan.
10.33 <sup>(19)</sup>	Placement Agency Agreement dated April 25, 2007, between the Registrant and Lehman Brothers Inc.
10.34 <sup>(20)</sup>	Letter agreement dated July 2, 2007, by and between the Registrant and Richard Alan Lerner, M.D.
10.35 <sup>(21)</sup>	Form of Purchase Agreement, dated October 25, 2007, by and between the Registrant and the various purchasers of shares of the Registrant's common stock.
10.36 <sup>(22)</sup> *	Amendment to Exclusive License of Technology Agreement dated November 5, 2007, by and between the Registrant and ISIS Innovation, Limited.
10.37 <sup>(23)</sup> #	Non-Employee Director Compensation Policy.
10.38 <sup>(23)</sup> #	Amended and Restated Change in Control Severance Benefit Plan.
10.39 <sup>(23)</sup> #	Deferred Compensation Plan, as amended.
10.40 <sup>(24)</sup> *	Amendment to Exclusive License of Technology Agreement dated November 3, 2009, by and between the Registrant and ISIS Innovation Limited.
10.41 <sup>(24)</sup> *	License Agreement, dated February 4, 2010, by and between the Registrant and Opherion, Inc.
10.42 <sup>(24)</sup> #	Agreement dated March 13, 2010 by and between the Registrant and Harry F. Hixson, Jr., Ph.D.

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<u>Exhibit Number</u>	<u>Description of Document</u>
10.43 <sup>(24)</sup> #	Letter agreement dated October 21, 2010 by and between the Registrant and Paul V. Maier.
10.44 <sup>(25)</sup>	Stipulation of Settlement in <i>In re Sequenom, Inc. Derivative Litigation</i> .
10.45 <sup>(26)</sup>	Securities Purchase Agreement, dated May 12, 2010, by and among the Registrant and the other parties named therein.
10.46 <sup>(26)</sup>	Registration Rights Agreement, dated May 12, 2010, by and among the Registrant and the other parties named therein.
10.47 <sup>(27)</sup> *	License Agreement, dated September 16, 2008, by and between the Registrant and The Chinese University of Hong Kong.
10.48 <sup>(28)</sup> #	New-Hire Equity Incentive Plan.
10.49 <sup>(29)</sup> *	License Agreement Dated May 3, 2011, between the Registrant and the Chinese University of Hong Kong.
10.50 <sup>(29)</sup>	Loan Agreement dated May 31, 2011, between the Registrant, Sequenom Center for Molecular Medicine, LLC, and Silicon Valley Bank.
10.51 <sup>(29)</sup>	First Amendment to Loan Agreement dated June 20, 2011, between the Registrant, Sequenom Center for Molecular Medicine, LLC, and Silicon Valley Bank.
10.52 <sup>(30)</sup> *	Sale and Supply Agreement dated July 8, 2011, between the Registrant and Illumina, Inc.
10.53 *	First Amendment to Sale and Supply Agreement dated September 29, 2011, between the Registrant and Illumina, Inc.
21.1	Subsidiaries of the Registrant.
23.1	Consent of Independent Registered Public Accounting Firm.
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities and Exchange Act, as amended.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-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.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Database.
#	Management contract or compensatory plan.
*	Certain confidential portions of this Exhibit have been omitted pursuant to a request for confidential treatment. Omitted portions have been filed separately with the Securities and Exchange Commission.
(1)	Incorporated by reference to the Registrant's Current Report on Form 8-K (No. 000-29101) filed June 6, 2006.
(2)	Incorporated by reference to the Registrant's Current Report on Form 8-K (No. 000-29101) filed January 15, 2010.
(3)	Incorporated by reference to the Registrant's Current Report on Form 8-K (No. 000-29101) filed March 4, 2009.
(4)	Incorporated by reference to the Registrant's Registration Statement on Form S-1 (No. 333-91665), as amended.
(5)	Incorporated by reference to the Registrant's Annual Report on Form 10-K (No. 000-29101) for the year ended December 31, 2006.

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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 Annual Report on Form 10-K (No. 000-29101) for the year ended December 31, 2003.
- (13) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q (No. 000-29101) for the quarter ended September 30, 2004.
- (14) Incorporated by reference to the Registrant's Current Report on Form 8-K (No. 000-29101) filed September 14, 2005.
- (15) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q (No. 000-29101) for the quarter ended September 30, 2005.
- (16) Incorporated by reference to the Registrant's Current Report on Form 8-K (No. 000-29101) filed April 3, 2006.
- (17) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q (No. 000-29101) for the quarter ended September 30, 2006.
- (18) Incorporated by reference to the Registrant's Current Report on Form 8-K (No. 000-29101) filed January 24, 2007.
- (19) Incorporated by reference to the Registrant's Current Report on Form 8-K (No. 000-29101) filed April 25, 2007.
- (20) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q (No. 000-29101) for the quarter ended June 30, 2007.
- (21) Incorporated by reference to the Registrant's Current Report on Form 8-K (No. 000-29101) filed October 26, 2007.
- (22) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q (No. 000-29101) for the quarter ended September 30, 2007.
- (23) Incorporated by reference to the Registrant's Annual Report on Form 10-K (No. 000-29101) for the year ended December 31, 2008.
- (24) Incorporated by reference to the Registrant's Annual Report on Form 10-K (No. 000-29101) for the year ended December 31, 2009.
- (25) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q (No. 000-29101) for the quarter ended March 31, 2010.
- (26) Incorporated by reference to the Registrant's Current Report on Form 8-K (No. 000-29101) filed May 13, 2010.
- (27) Incorporated by reference to the Registrant's Annual Report on Form 10-K (No. 000-29101) for the year ended December 31, 2010.
- (28) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q (No. 000-29101) for the quarter ended March 31, 2011.
- (29) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q (No. 000-29101) for the quarter ended June 30, 2011.
- (30) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q (No. 000-29101) for the quarter ended September 30, 2011.

## 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 9, 2012

SEQUENOM, INC.

/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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
/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 9, 2012
/s/ PAUL V. MAIER Paul V. Maier	Chief Financial Officer (Principal Financial and Accounting Officer)	March 9, 2012
/s/ ERNST-GUNTER AFTING, PH.D., M.D. Ernst-Gunter Afting, Ph.D., M.D.	Director	March 9, 2012
/s/ KENNETH F. BUECHLER, PH.D. Kenneth F. Buechler, Ph.D.	Director	March 9, 2012
/s/ JOHN A. FAZIO John A. Fazio	Director	March 9, 2012
/s/ RICHARD A. LERNER, M.D. Richard A. Lerner, M.D.	Director	March 9, 2012
/s/ RONALD M. LINDSAY, PH.D. Ronald M. Lindsay, Ph.D.	Executive Vice President and Director	March 9, 2012
/s/ DAVID PNDARVIS David Pendarvis	Director	March 9, 2012
/s/ CHARLES SLACIK Charles Slacik	Director	March 9, 2012

**SEQUENOM, INC.**  
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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, 2011 and 2010, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2011. 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, 2011 and 2010, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2011, 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, 2011, 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 9, 2012 expressed an adverse opinion on the effectiveness of internal control over financial reporting.

/s/ Ernst & Young LLP

San Diego, California  
March 9, 2012

**SEQUENOM, INC.**  
**CONSOLIDATED BALANCE SHEETS**  
**(In thousands, except share and per share information)**

	December 31,	
	2011	2010
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 28,926	\$ 116,647
Marketable securities	55,290	18,833
Restricted cash	66	1,404
Accounts receivable, net	6,972	6,911
Inventories	8,729	5,605
Prepaid expenses and other assets	3,533	2,387
Total current assets	103,516	151,787
Equipment and leasehold improvements, net	19,629	11,038
Intangible assets, net	1,154	773
Goodwill	10,007	10,007
Other assets	1,241	674
Total assets	<u>\$ 135,547</u>	<u>\$ 174,279</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 8,435	\$ 5,958
Accrued expenses	15,743	9,932
Deferred revenue	2,137	2,624
Long-term debt and obligations, current portion	1,902	938
Other current liabilities	787	15
Total current liabilities	29,004	19,467
Deferred revenue, less current portion	780	518
Long-term debt and obligations, less current portion	13,273	902
Other long-term liabilities	1,102	2,660
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, 2011 or 2010, respectively.	—	—
Common stock, par value \$0.001; authorized shares—185,000,000, issued and outstanding shares—99,348,623 and 98,849,381 at December 31, 2011 and 2010, respectively	99	99
Additional paid-in capital	883,006	867,977
Accumulated other comprehensive income	570	786
Accumulated deficit	(792,287)	(718,130)
Total stockholders' equity	91,388	150,732
Total liabilities and stockholders' equity	<u>\$ 135,547</u>	<u>\$ 174,279</u>

See accompanying notes.

**SEQUENOM, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(In thousands, except per share information)**

	Year ended December 31,		
	2011	2010	2009
Revenues:			
Genetic analysis product sales and services	\$ 47,588	\$ 44,905	\$ 37,769
Diagnostic services	8,319	2,554	94
Total revenues	<u>55,907</u>	<u>47,459</u>	<u>37,863</u>
Costs of revenues:			
Cost of genetic analysis product sales and services	13,283	15,031	14,158
Cost of diagnostic services	10,031	3,965	412
Total cost of revenues	<u>23,314</u>	<u>18,996</u>	<u>14,570</u>
Gross margin	<u>32,593</u>	<u>28,463</u>	<u>23,293</u>
Operating expenses:			
Research and development	53,585	43,431	37,454
Selling and marketing	31,087	28,387	26,845
General and administrative	22,185	22,280	28,127
Litigation settlement, net	—	55,384	—
Restructuring	—	—	1,589
Total operating expenses	<u>106,857</u>	<u>149,482</u>	<u>94,015</u>
Loss from operations	(74,264)	(121,019)	(70,722)
Interest income	71	162	442
Gain (loss) on marketable securities	42	111	(1,914)
Interest expense	(366)	(190)	(261)
Other income, net	455	82	1,560
Loss before income taxes	(74,062)	(120,854)	(70,895)
Income tax (expense) benefit	(95)	10	(117)
Net loss	<u>\$ (74,157)</u>	<u>\$ (120,844)</u>	<u>\$ (71,012)</u>
Net loss per share, basic and diluted	<u>\$ (0.75)</u>	<u>\$ (1.69)</u>	<u>\$ (1.16)</u>
Weighted average shares outstanding, basic and diluted	<u>99,143</u>	<u>71,697</u>	<u>61,171</u>

See accompanying notes.

**SEQUENOM, INC.**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
(In thousands, except share information)

	Common Stock		Additional Paid-In Capital	Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
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
Vesting of restricted stock, net	23,224	—	1,519	—	—	1,519
Exercise of stock options	480,153	1	1,145	—	—	1,146
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)	—	(34)
Translation adjustment	—	—	—	(264)	—	(264)
Comprehensive loss	—	—	—	—	—	(121,142)
Stock-based compensation	—	—	10,865	—	—	10,865
Vesting of restricted stock, net	70,911	—	648	—	—	648
Exercise of stock options	1,036,165	1	2,608	—	—	2,609
Purchases under Employee Stock Purchase Plan	202,089	—	704	—	—	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	\$ 99	\$ 867,977	\$ 786	\$(718,130)	\$ 150,732
Net loss	—	—	—	—	(74,157)	(74,157)
Unrealized gain on available-for-sale securities	—	—	—	10	—	10
Translation adjustment	—	—	—	(226)	—	(226)
Comprehensive loss	—	—	—	—	—	(74,373)
Stock-based compensation	—	—	10,579	—	—	10,579
Vesting of restricted stock, net	91,508	—	1,483	—	—	1,483
Issuance of warrants for license	—	—	1,155	—	—	1,155
Exercise of stock options	253,835	—	977	—	—	977
Purchases under Employee Stock Purchase Plan	153,899	—	835	—	—	835
Balance at December 31, 2011	99,348,623	\$ 99	\$ 883,006	\$ 570	\$(792,287)	\$ 91,388

See accompanying notes.

**SEQUENOM, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(In thousands)

	Year ended December 31,		
	2011	2010	2009
<b>Operating activities</b>			
Net loss	\$ (74,157)	\$ (120,844)	\$ (71,012)
Adjustments to reconcile net loss to net cash used in operating activities:			
Litigation settlement, net of revaluation gains	—	55,046	—
Stock-based compensation	12,062	11,513	12,269
Warrant issued for license fee	1,155	—	—
License fee payable	1,500	—	—
Bad debt expense	(21)	873	(139)
Depreciation and amortization	7,130	5,592	5,201
Loss on marketable securities	—	—	1,914
Loss on disposal of fixed assets	7	235	193
Settlement of SensiGen, LLC claim	—	—	1,522
Contingent consideration fair value adjustment	—	32	514
Deferred rent	(764)	(700)	(569)
Other non-cash items	50	179	7
Changes in operating assets and liabilities:			
Accounts receivable, net	(88)	581	1,892
Inventories	(3,142)	2,045	2,923
Prepaid expenses and other assets	(1,699)	231	(1,266)
Accounts payable and accrued expenses	6,936	2,179	(1,733)
Deferred revenue	(223)	1,016	267
Other liabilities	(15)	(559)	(691)
Net cash used in operating activities	<u>(51,269)</u>	<u>(42,581)</u>	<u>(48,708)</u>
<b>Investing activities</b>			
Purchases of equipment, leasehold improvements, and intangible assets	(16,198)	(4,927)	(8,699)
Purchases of marketable securities	(141,666)	(25,782)	(30,297)
Acquisition of SensiGen, LLC, net of cash acquired	—	—	(2,017)
Proceeds from the sale of equipment	—	86	—
Proceeds from sales of marketable securities	54,907	497	3,363
Maturities of marketable securities	50,360	22,180	45,000
Release (increase) of restricted cash	1,338	43	(49)
Net cash (used in) provided by investing activities	<u>(51,259)</u>	<u>(7,903)</u>	<u>7,301</u>
<b>Financing activities</b>			
Payments on borrowings of debt and obligations	(1,807)	(1,317)	(1,656)
Borrowings on term loan	15,000	—	—
Proceeds from private placement, net of issuance costs	—	138,344	—
Proceeds from exercise of warrants, stock options, and ESPP purchases	1,812	3,313	1,905
Net cash provided by financing activities	<u>15,005</u>	<u>140,340</u>	<u>249</u>
Net (decrease) increase in cash and cash equivalents	(87,523)	89,856	(41,158)
Effect of exchange rate changes on cash and cash equivalents	(198)	(128)	(261)
Cash and cash equivalents at beginning of year	116,647	26,919	68,338
Cash and cash equivalents at end of year	<u>\$ 28,926</u>	<u>\$ 116,647</u>	<u>\$ 26,919</u>
<b>Supplemental disclosure of cash flow information:</b>			
Interest paid	<u>\$ 237</u>	<u>\$ 203</u>	<u>\$ 247</u>
<b>Supplemental non-cash items:</b>			
Investing activities:			
Equipment purchased under capital lease obligation	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 366</u>
Financing activities:			
Issuance of common stock related to litigation settlement	<u>\$ —</u>	<u>\$ 55,046</u>	<u>\$ —</u>

See accompanying notes.

**SEQUENOM, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
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**1. Summary of Significant Accounting Policies**

We are a molecular diagnostic testing and genetics analysis company committed to providing molecular diagnostic testing services, and research use only 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, and other medical conditions such as oncology, infectious diseases and autoimmunity.

***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 have been eliminated in consolidation.

***Use of Estimates***

The preparation of financial statements in conformity with GAAP 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.

***Revenue Recognition***

Our revenue is generated primarily from the sale of products and services. Genetic analysis product sales and services revenue primarily consists of sales of system instrumentation and consumables used in genetic analysis, including extended warranty services associated with the instrumentation as well as other amounts earned under contract research agreements. Diagnostic services revenues consist of performing laboratory-developed tests, or LDTs, for cystic fibrosis, or CF, carrier screening, fetal Rhesus D, or RHD, genotyping, age-related macular degeneration, or AMD, and MaterniT21 PLUS.

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. 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.

**SEQUENOM, INC.**  
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In October 2009, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2009-13, *Multiple-Deliverable Revenue Arrangements*. The new standard changes the requirements for establishing separate units of accounting in a multiple element arrangement and requires the allocation of arrangement consideration to each deliverable to be based on the relative selling price. We adopted the standard and, effective as of January 1, 2011, when a collaboration arrangement or sales arrangement contains multiple elements we allocate revenue to each element based on a selling price hierarchy. The selling price for a deliverable is based on its vendor specific objective evidence, or VSOE, if available, third-party evidence, or TPE, if VSOE is not available, or estimated selling price, if neither VSOE nor TPE is available. We limit the amount of revenue recognition for delivered elements to the amount that is not contingent on the future delivery of products or services, future performance obligations, or subject to customer-specified return or refund privileges.

We evaluate deliverables in a multiple-element arrangement to determine whether each represents a separate unit of accounting. A deliverable constitutes a separate unit of accounting when it has standalone value to the customer and there are no customer-negotiated refund or return rights for the delivered elements. Items are considered to have standalone value when they are sold separately by any vendor or when the customer could sell the item on a standalone basis. In instances when the aforementioned criteria are not met, the deliverable is combined with the undelivered elements and the allocation of the arrangement consideration and revenue recognition is determined for the combined unit as a single unit. Allocation of the consideration is determined by management at the arrangement inception on the basis of each unit's relative selling price.

We establish VSOE of selling price using the price charged for a deliverable when sold separately and, in rare instances, using the price established by management having the relevant authority. In order to establish VSOE of selling price, we must regularly sell the product or service on a stand-alone basis with a substantial majority priced within a relatively narrow range. VSOE of selling price is usually the midpoint of that range. If there are not a sufficient number of standalone sales and VSOE of selling price cannot be determined, then we consider whether third party evidence can be used to establish selling price. Due to the lack of similar products and services sold by other companies within the industry, we have not established selling price using third-party evidence. If neither VSOE nor third party evidence of selling price exists, we determine our best estimate of selling price. The best estimate of selling price is established considering internal factors such as historical selling prices, pricing practices and controls, and customer segment pricing strategies.

Diagnostic revenues from Sequenom CMM have been recognized on a cash basis due to the lack of contractual reimbursement 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. Patients have established maximum out-of-pocket costs for amounts not covered by their insurance carrier and we bill the patient directly for these amounts in the form of co-pays and deductibles. 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. We will continue to recognize revenue upon cash collection until we can reliably estimate the amount that would be ultimately collected.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
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***Accounts Receivable***

We invoice our genetic analysis product sales and services as orders are shipped and any other contractual obligations are met. Our contracts typically require payment within 30 to 60 days of the date of invoice. We maintain allowances for doubtful accounts for estimated losses resulting from the inability of our clients to make required payments. We specifically analyze accounts receivable and historical bad debts, client credit, current economic trends, and changes in client payment trends when evaluating the adequacy of the allowance for doubtful accounts. Account balances are charged-off against the allowance when it is probable the receivable will not be recovered. Allowance for doubtful accounts was \$771,000 and \$1.2 million at December 31, 2011 and 2010, respectively.

We bill third-party payors for our LDTs upon providing test results to ordering physicians. As such, we take assignment of benefits and the risk of collection with third-party payors. We continue to monitor the collection history for third-party payors. We do not record accounts receivable for billings to third-party payors as these revenues are recognized on a cash basis.

We cannot guarantee that we will continue to experience the same credit loss rates that we have in the past. Measurement of such losses requires consideration of historical loss experience, including the need to adjust for current conditions, and judgments about the probable effects of relevant observable data, including present economic conditions such as delinquency rates and financial health of specific customers. We consider all available information in our assessments of the adequacy of the reserves for uncollectible accounts. For billings directly to physician offices or to uninsured participants, we continue to recognize revenue on a cash basis.

**SEQUENOM, INC.**  
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**Concentration of Risks**

Financial instruments that we are potentially subject to credit risk principally consist of accounts receivables. We grant credit generally on an unsecured basis to customers throughout North America, Europe, and Asia, except for China that are on a secured basis until a collection history is established. 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:

<u>Region</u>	<u>December 31,</u> <u>2011</u>	<u>Percent of</u> <u>receivable</u> <u>balance</u>	<u>December 31,</u> <u>2010</u>	<u>Percent of</u> <u>receivable</u> <u>balance</u>
		<small>(In thousands, except for percentages)</small>		
North America	\$ 2,912	42%	\$ 3,723	54%
Europe	2,204	31%	1,903	28%
Asia	1,856	27%	1,285	18%
Total	<u>\$ 6,972</u>	<u>100%</u>	<u>\$ 6,911</u>	<u>100%</u>

At December 31, 2011, no single 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, 2011.

We are dependent on our suppliers and contract manufacturers to provide raw materials, drugs and devices of appropriate quality and reliability and to meet applicable regulatory requirements. In certain cases, we rely on single sources of supply. Consequently, in the event that supplies are delayed or interrupted for any reason, our ability to develop and produce our products could be impaired, which could have a material adverse effect on our business, financial condition and results of operations.

**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 prior to January 1, 2011 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,

**SEQUENOM, INC.**  
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amortization of revenue is adjusted prospectively. On January 1, 2011, we elected to prospectively adopt ASU 2010-17, "Milestone Method of Revenue Recognition". Under the milestone method, contingent consideration received from the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved, which we believe is more consistent with the substance of our performance under our various license and collaboration agreements. A milestone is defined as an event (i) that can only be achieved based in whole or in part on either the entity's performance or on the occurrence of a specific outcome resulting from the entity's performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, and (iii) that would result in additional payments being due to the entity. A milestone is substantive if the consideration earned from the achievement of the milestone is consistent with our performance required to achieve the milestone or the increase in value to the collaboration resulting from our performance, relates solely to our past performance, and is reasonable relative to all of the other deliverables and payments within the arrangement.

***Shipping and Handling Costs***

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

***Cash, Cash Equivalents, and Marketable Securities***

Cash equivalents consist of short-term, highly liquid investments with original maturities of three months or less when purchased. Investments with an original maturity of more than three months are considered marketable securities and have been classified by management as available-for-sale. Such investments are carried at fair value, with unrealized gains and losses recorded as a component of stockholders' equity.

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, 2011 and 2010, 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 measurements are 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 years ended December 31, 2011 and 2010 were \$42,000 and \$111,000, respectively, and gross realized losses were immaterial. Gross realized gains for the year ended December 31, 2009 were immaterial and gross realized losses were \$1.9 million.

At December 31, 2011 and 2010, we had \$2.0 million, respectively, of principal invested in auction rate securities (ARS) with an estimated fair value of \$0, 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, 2011 and 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. 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,

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counterparty risk, and ongoing strength and quality of market credit and liquidity. Based on these factors our remaining ARS continues to have an estimated fair value of \$0 since December 31, 2009.

***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*—Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.

*Level 2*—Include other inputs that are directly or indirectly observable in the marketplace.

*Level 3*—Unobservable inputs that are supported by little or no market activities, therefore requiring an entity to develop its own assumptions. As of December 31, 2011 and 2010, we had no assets or liabilities measured at fair value on a recurring basis within the Level 3 hierarchy.

We classify our cash equivalents and marketable securities within Level 1 or Level 2. This is because we value our cash equivalents and marketable securities using quoted market prices or alternative pricing sources and models utilizing market observable inputs.

The following table summarizes our fair value hierarchy for assets and liabilities measured at fair value on a recurring basis (in thousands):

<u>Description</u>	<u>As of December 31, 2011</u>	<u>Level 1</u>	<u>Level 2</u>
Cash equivalents	\$ 13,572	\$ 13,097	\$ 475
Government and agency backed debt securities	5,072	—	5,072
Mutual funds	323	323	—
Certificates of deposit	4,909	—	4,909
U.S. treasury securities	44,986	44,986	—
Total	<u>\$ 68,862</u>	<u>\$58,406</u>	<u>\$10,456</u>

<u>Description</u>	<u>As of December 31, 2010</u>	<u>Level 1</u>	<u>Level 2</u>
Cash equivalents	\$ 107,126	\$ 107,126	\$ —
Government and agency backed debt securities	8,081	—	8,081
Mutual funds	382	382	—
Certificates of deposit	5,372	—	5,372
U.S. treasury securities	4,998	4,998	—
Total	<u>\$ 125,959</u>	<u>\$ 112,506</u>	<u>\$ 13,453</u>

**SEQUENOM, INC.**  
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There were no transfers in or out of Level 2 and Level 3 investments during the years ended December 31, 2011 and 2010.

***Restricted Cash***

Restricted cash relates to cash that is pledged as collateral for letters of credit issued by us, primarily in connection with performance guarantees.

***Inventories***

Inventories are valued at the lower of cost (first-in, first-out) or market value (net realizable value). We estimate the recoverability of our inventory by reference to our internal estimates of future demands and product life cycles, including expiration. During 2011, slow-moving and obsolete inventory reserves of \$1.3 million were charged against cost of goods sold. Inventories are shown net of total reserves of \$1.9 million and \$1.3 million at December 31, 2011 and 2010, 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.

Depreciation expense for the years ended December 31, 2011, 2010, and 2009 was \$6.7 million, \$5.2 million and \$5.1 million, respectively, and included \$122,000, \$122,000, and \$92,000 of depreciation on equipment under capital lease for the years ended December 31, 2011, 2010, and 2009, respectively.

All long-lived assets are reviewed for impairment in value when changes in circumstances dictate, based upon undiscounted future operating cash flows, and appropriate losses are recognized and reflected in current earnings, to the extent the carrying amount of an asset exceeds its estimated fair value determined by the use of appraisals, discounted cash flow analyses, or comparable fair values of similar assets.

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***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, 2011 were as follows (in thousands):

Balance as of December 31, 2008	\$ 606
Additions charged to cost of revenues	199
Repairs, replacements, and reduction in liability requirements	<u>(630)</u>
Balance as of December 31, 2009	\$ 175
Additions charged to cost of revenues	195
Repairs, replacements, and reduction in liability requirements	<u>(218)</u>
Balance as of December 31, 2010	\$ 152
Additions charged to cost of revenues	94
Repairs, replacements and reduction in liability requirements	<u>(45)</u>
Balance as of December 31, 2011	<u>\$ 201</u>

***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 intangible assets that have finite useful lives, 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, 2011 and 2010, 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. 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.

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Intangible assets consisted of the following (in thousands):

	Weighted Average Life	December 31, 2011		December 31, 2010	
		Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Clinical data collections	5	\$ 13,552	\$ (13,552)	\$ 13,552	\$ (13,552)
Purchased patent rights and licenses	5	6,408	(5,298)	5,608	(4,902)
Lab accreditation	5	117	(73)	117	(50)
Total		<u>\$ 20,077</u>	<u>\$ (18,923)</u>	<u>\$ 19,277</u>	<u>\$ (18,504)</u>

Intangible assets are amortized using the straight-line method over their estimated useful lives. Amortization of intangible assets for the years ended December 31, 2011, 2010, and 2009 was \$419,000, \$357,000, and \$107,000, respectively.

The following table is a schedule of future estimated amortization expense at December 31, 2011 (in thousands):

2012	\$ 490
2013	125
2014	74
2015	74
2016	74
Thereafter	317
Total	<u>\$ 1,154</u>

#### ***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, and Japanese subsidiaries are measured using, respectively, the Euro (EUR), Great British pound (GBP), 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) in equity. Transactions denominated in currencies other than the local currency are recorded based on

**SEQUENOM, INC.**  
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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, 2011, 2010, and 2009.

***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. When we establish or reduce the valuation allowance against deferred tax assets, our provision for income taxes will increase or decrease, respectively, in the period such determination is made. As of December 31, 2011 and 2010, 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.

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***Stock-based Compensation***

We measure and recognize compensation expense for all stock-based payments made to employees and directors based on estimated fair value, net of an estimated forfeiture rate. These stock-based awards include stock options, stock purchase rights under the Employee Stock Purchase Plan (ESPP), and restricted stock. We estimate the fair value of stock options granted and stock purchases under our ESPP using the Black-Scholes-Merton (BSM) option-pricing model. The fair value of our restricted stock units is based on the market price of our common stock on the date of grant. The determination of fair value of stock-based awards using the BSM model requires the use of certain estimates and highly judgmental assumptions that affect the amount of stock-based compensation expense recognized in our consolidated statements of income. These include estimates of the expected volatility of our stock price, expected life of an award, expected dividends, and the risk-free interest rate. We amortize the fair value of stock-based compensation on a straight-line basis over the requisite service periods of the awards. If any of the assumptions used in the BSM model change significantly, stock-based compensation expense may differ materially from what we have recorded in the current period. Our net loss for the years ended December 31, 2011, 2010, and 2009, included the following compensation expense related to our stock-based compensation awards (in thousands):

	<u>2011</u>	<u>2010</u>	<u>2009</u>
Research and development expense	\$ 4,859	\$ 4,186	\$ 3,885
Selling and marketing expense	3,289	3,205	3,689
General and administrative expense	3,914	4,122	4,695
	<u>\$ 12,062</u>	<u>\$ 11,513</u>	<u>\$ 12,269</u>

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 stock-based compensation cost as a result of the full valuation allowance of our net deferred tax assets and our net operating loss carryforwards.

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. Stock-based compensation for options granted to non-employees included in total stock-based compensation for the years ended December 31, 2011, 2010, and 2009, was \$65,000, \$229,000, and \$273,000, 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, 2011, 2010, and 2009 totaling \$6,000, \$42,000, and \$1,000; \$0, \$47,000, and \$59,000; and \$59,000, \$140,000, and \$213,000, 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.

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**Net Loss Per Share**

Basic and diluted net loss applicable to common stock per share is computed using the weighted average number of common shares outstanding during the period. Shares used in calculating basic and diluted net loss per common share exclude as antidilutive the following common share equivalents:

	2011	Years ended December 31, 2010	2009
Options to purchase common stock	4,833,075	3,875,636	3,507,803
Restricted stock not yet vested and released	974,940	1,143,551	1,328,551
Warrants to purchase common stock	250,000	59,035	59,035
	<u>6,058,015</u>	<u>5,078,222</u>	<u>4,895,389</u>

In future periods, if we report net income and the common share equivalents for our convertible senior notes are dilutive, the common stock equivalents will be included in the weighted average shares computation and interest expense related to the notes will be added back to net income to calculate diluted earnings per share.

**Recent Accounting Pronouncements**

In September 2011, the FASB issued an ASU related to Testing Goodwill for Impairment that gives companies the option to first perform a qualitative assessment to determine whether it is more likely than not (a likelihood of more than 50%) that the fair value of a reporting unit is less than its carrying amount. Under this guidance, only if we conclude that it is more likely than not that the fair value of a reporting unit is less than its carrying amount are we required to perform the two-step test. Otherwise, we can skip the two-step test. This guidance is effective for fiscal years beginning after December 15, 2011 with early adoption permitted. We have early adopted this guidance and performed the qualitative assessment during our annual goodwill impairment assessment.

In April 2010, the FASB issued an 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 was effective for us beginning January 1, 2011. The adoption of this update did not have a material impact on our consolidated financial statements. We do not expect to receive any significant milestone revenue from our current license and collaboration agreements.

In January 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 was effective for us beginning January 1, 2011. The adoption of this update did not have a material impact on our consolidated financial statements.

In October 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

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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 was effective for us beginning January 1, 2011. The adoption of this update did not have a material impact on our consolidated financial statements.

***New Accounting Standards Not Yet Adopted***

In June 2011, the FASB issued an ASU related to the Presentation of Comprehensive Income. The guidance requires an entity to present items of net income and other comprehensive income, or OCI, and total comprehensive income either in a single continuous statement of comprehensive income or two separate but continuous statements. We will no longer be allowed to present OCI in the statement of stockholders' equity. Earnings per share would continue to be based on net income. Although existing guidance related to items that must be presented in OCI has not changed, companies will be required to display reclassification adjustments for each component of OCI in both net income and OCI. Also, companies will need to present the components of other comprehensive income in their interim and annual financial statements. This guidance is required to be implemented retrospectively during interim and annual periods beginning after December 15, 2011, which will be our fiscal year 2012. The adoption of this update is not expected to have a material impact on our consolidated financial statements.

In May 2011, the FASB issued an ASU related to Fair Value Measurements and Disclosures that clarified and amended the wording used to describe many of the requirements in GAAP for measuring fair value and for disclosing information about fair value measurements. The FASB also clarified the intent of existing fair value measurement requirements. The new and revised disclosures are required to be implemented prospectively during interim and annual periods beginning after December 15, 2011, which will be our fiscal year 2012. Early adoption is not permitted. The adoption of this update is not expected to have a material impact on our consolidated financial statements.

**2. Other Financial Information**

The following table provides information regarding our genetic analysis product sales and services revenues (in thousands):

	<u>2011</u>	<u>2010</u>	<u>2009</u>
Product sales	\$39,709	\$ 37,388	\$ 31,223
Maintenance services	5,227	5,034	4,310
Contract research	2,646	2,483	2,209
Other	6	—	27
	<u>\$47,588</u>	<u>\$44,905</u>	<u>\$37,769</u>

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The following is a summary of our marketable securities (in thousands):

	December 31, 2011			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Government and agency backed debt securities	\$ 5,067	\$ 5	\$ —	\$ 5,072
Mutual funds	224	100	(1)	323
Certificates of deposit	4,901	11	(3)	4,909
U.S. treasury securities	44,971	15	—	44,986
<b>Total available-for-sale securities</b>	<b>\$55,163</b>	<b>\$ 131</b>	<b>\$ (4)</b>	<b>\$55,290</b>

	December 31, 2010			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Government and agency backed debt securities	\$ 8,077	\$ 4	\$ —	\$ 8,081
Mutual funds	237	145	—	382
Certificates of deposit	5,376	—	(4)	5,372
U.S. treasury securities	4,994	4	—	4,998
<b>Total available-for-sale securities</b>	<b>\$18,684</b>	<b>\$ 153</b>	<b>\$ (4)</b>	<b>\$18,833</b>

As of December 31, 2011, we had 20 available-for-sale securities in a gross unrealized loss position, which had been in such position for less than twelve months. There were no unrealized losses due to credit issues for the periods presented. There were no impairments considered other-than-temporary as it is management's intention and ability to hold the securities until maturity or a recovery of the cost basis. The following table shows the fair values and the gross unrealized losses of our available-for-sale securities that were in an unrealized loss position as of December 31, 2011 and 2010 aggregated by investment category (in thousands):

	December 31, 2011		December 31, 2010	
	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
Government and agency backed debt securities	\$ 1,011	\$ (1)	\$ —	\$ —
Certificates of deposit	3,701	(3)	4,691	(4)
<b>Total</b>	<b>\$ 4,712</b>	<b>\$ (4)</b>	<b>\$4,691</b>	<b>\$ (4)</b>

Realized gains and losses are determined based on the specific identification method and are reported in other income (loss), net, in the consolidated statements of operations. Gross realized gains and losses on sales of available-for-sale securities were immaterial for the years ended December 31, 2011 and 2010. As of December 31, 2011, all of our available-for-sale securities were due within one year.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
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The components of inventories were as follows (in thousands):

	December 31,	
	2011	2010
Raw materials	\$7,069	\$ 3,738
Work in process	113	45
Finished goods	1,547	1,822
Total	<u>\$8,729</u>	<u>\$5,605</u>

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

	December 31,	
	2011	2010
Laboratory equipment	\$ 32,864	\$ 23,562
Leasehold improvements	6,819	5,319
Office furniture and equipment	15,486	11,900
	55,169	40,781
Less accumulated depreciation and amortization	<u>(35,540)</u>	<u>(29,743)</u>
	<u>\$ 19,629</u>	<u>\$ 11,038</u>

### 3. Acquisitions

#### *SensiGen, LLC*

In February 2009, we completed a taxable acquisition of certain assets and assumption of certain liabilities of SensiGen, LLC (SensiGen). The acquisition of the SensiGen assets provided us with intellectual property related to certain molecular diagnostics for women's health and cancer. The acquisition resulted in the recognition of goodwill at the time of purchase of approximately \$7.0 million and is 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 was contingently payable to SensiGen upon the completion of certain triggering events occurring prior to the end of the agreement period of February 2012 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. The remaining contingent consideration was remeasured and the liability increased to \$541,000 as of December 31, 2009. During 2010, we satisfied additional obligations with an aggregate cash payment of \$520,000. As of December 31, 2010, we measured the remaining contingent consideration and increased the remaining accrual balance to \$53,000. Since April 2011 we have not believed the remaining trigger events are likely to occur prior to the end of the period specified in the Agreement and therefore we reversed the \$53,000 previously accrued for the remaining contingent consideration.

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**4. Litigation Settlement**

Litigation settlement was \$0, \$55.4 million, and \$0 for the years ended December 31, 2011, 2010, and 2009, respectively. 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 paid \$14.0 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 approved share settlement issued to plaintiffs' counsel in August 2010 and the revaluation to fair value for the remaining shares that were issued to the members of the plaintiffs' class on 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. Segment Reporting**

We operate our business on the basis of two reportable segments, Molecular Diagnostics (including Sequenom CMM) and Genetic Analysis. A further description of the operations of these segments is below. For the years ended December 31, 2011, 2010, and 2009, we generated approximately 85.1%, 94.6%, and 99.8%, respectively, of our revenues from our Genetic Analysis segment. Product sales and services revenues for this segment were derived from sales of consumables, including our SpectroCHIP arrays used with our iPLEX assay and other assays, MassARRAY hardware, maintenance agreements, sales and licensing of our proprietary software, and contract research services. Diagnostic revenues accounted for approximately 14.9%, 5.4%, and 0.2% of our revenues for the years ended December 31, 2011, 2010, and 2009, respectively, and were primarily derived from the sale of Sequenom CMM's Cystic Fibrosis Carrier Screening LDT, and to a much lesser extent the RHD genotyping LDT. Collections from the sale of Sequenom CMM's AMD LDT and MaterniT21 LDT were not significant for the periods presented due to commencement of their commercialization in the second and fourth quarters of 2011, respectively. 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.

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We evaluate segment performance based on a revenue and operating income (loss) basis exclusive of general and administrative expenses, stock-based compensation, litigation settlement expense, other indirect costs, and certain other adjustments, which are not allocated to our segments for performance assessment by our chief operating decision maker. Unallocated operating expenses excluded from our segments for performance assessment represent expenses that do not reflect, according to criteria established by us, operating expenses associated with our reportable segment activities. No evaluation of segment performance or allocation of resources is done by our chief operating decision maker in consideration of discrete segment assets and we do not discretely allocate assets to our operating segments. Intersegment revenues and transfers are immaterial. The accounting policies of the reportable segments are the same as those described in the summary of significant accounting policies.

The following table sets forth our revenues and operating loss from our Molecular Diagnostic (including Sequenom CMM) and Genetic Analysis segments for the years ended December 31, 2011, 2010, and 2009, respectively (in thousands):

	<u>2011</u>	<u>2010</u>	<u>2009</u>
<b>Revenues:</b>			
Molecular Diagnostics	\$ 8,319	\$ 2,554	\$ 94
Genetic Analysis	47,588	44,905	37,769
	<u>\$ 55,907</u>	<u>\$ 47,459</u>	<u>\$ 37,863</u>
<b>Operating (loss) income:</b>			
Molecular Diagnostics	\$(43,799)	\$ (36,216)	\$ (27,034)
Genetic Analysis	14,216	11,873	4,379
Unallocated	<u>(44,681)</u>	<u>(96,676)</u>	<u>(48,067)</u>
	<u>\$ (74,264)</u>	<u>\$ (121,019)</u>	<u>\$ (70,722)</u>

## 6. Debt and Obligations

### *Debt*

In May 2011, we and our wholly-owned subsidiary Sequenom CMM entered into a Loan and Security Agreement (Loan Agreement) with Silicon Valley Bank (SVB) that allows for term loans of up to \$20.0 million, revolving cash borrowings of up to \$10.0 million, as well as letters of credit all under a secured credit facility. All borrowings under the Loan Agreement are secured by substantially all of our and Sequenom CMM's assets, except for intellectual property, and are subject to certain other exceptions. The Loan Agreement includes limitations on our ability, among other things, to incur debt, to grant liens, to make certain investments, to make certain restricted payments such as dividend payments, and to dispose of assets, as well as requirements to meet a number of affirmative and negative covenants.

Under the Loan Agreement, term loans bear interest at the rate fixed on the date of funding equal to the U.S. treasury rate plus 3.25% per annum (3.65% - 4.24% at December 31, 2011). We may borrow under the term loan through August 31, 2012. The term loan borrowings are to be repaid in 33 equal installments of principal, plus accrued interest commencing on September 1, 2012. The term loan requires a final payment of the greater of \$420,000 or 3.5% of all advances made under the term loan, in addition to principal repayments, at the loan maturity date, which is May 1, 2015. We have the option to prepay the outstanding balance of the term loan in full, subject to the final payment, and a prepayment fee of 2% of the principal amount prepaid if the prepayment occurs before August 31, 2012. As of December 31, 2011, we had borrowed \$15.0 million under this term loan.

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Under the terms of the revolving credit facility, we may borrow up to \$10 million based on percentage of eligible accounts receivable, as defined within the Loan Agreement. Amounts outstanding under the revolving credit facility accrue interest, payable monthly, at a floating rate equal to 1% over the U.S. prime rate, with principal due the maturity date of May 31, 2014. We have the option to terminate the revolving credit facility prior to the loan maturity date and repay the outstanding balance in full, subject to a termination fee between 1% to 3% depending upon when prepayment occurs. At December 31, 2011, no amounts had been drawn under this credit line.

The following is a schedule of future maturities on our term loans at December 31, 2011 (in thousands):

<u>Year Ending December 31,</u>	<u>Payments</u>
2012	\$ 1,902
2013	5,473
2014	5,522
2015	2,278
	<u>\$15,175</u>

At December 31, 2011 we were in compliance with all covenants under the Loan Agreement. These include a minimum liquidity covenant requiring us to maintain with SVB unrestricted cash and marketable securities plus available amounts equal to or greater than the sum of all indebtedness owed to SVB plus our operating liquidity.

In connection with our acquisition of SensiGen in February 2009, we assumed two loans with an aggregate balance at the closing date of approximately \$3.2 million. The first loan of approximately \$0.3 million had a stated interest rate of 1% with all payments deferred until March 2013. The second loan of approximately \$2.9 million had a stated interest rate of 7% with monthly principal payments of approximately \$68,000 through September 2012. Both of these loans were repaid during 2011.

#### ***Capital Lease***

In April 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. As of December 31, 2011, we had approximately \$33,000 outstanding on this capital lease, which we expect will be repaid in full during 2012.

### **7. Commitments and Contingencies**

#### ***Building Leases***

We lease office and manufacturing facilities under various non-cancellable operating lease agreements. Facility leases generally provide for periodic rent increases, and many contain escalation clauses and renewal options. Certain leases require the Company to pay property taxes and routine maintenance. We are headquartered in San Diego, California and lease facilities in the United States, Germany, China, United Kingdom, and Japan. These leases have various terms that expire at various dates through December 2016. Total rent expense under these leases was approximately \$5.2 million, \$5.3 million, and \$5.4 million in 2011, 2010, and 2009, respectively.

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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.

Minimum future annual obligations under non-cancelable operating lease commitments for years ending after at December 31, 2011 are as follows (in thousands):

2012	\$ 7,465
2013	7,138
2014	7,004
2015	5,886
2016	633
Thereafter	—
	<u>\$28,126</u>

On November 9, 2011, we entered into a lease and a sublease agreement for two new facilities located in San Diego, California, and Durham, North Carolina, respectively. The lease has a target commencement date of January 1, 2012 and has an initial term through January 2016. The sublease has a target commencement date of March 1, 2012 and has an initial term through December 2016. We are making certain leasehold improvements to each of these facilities, which we will amortize over the shorter of the lease term or their expected useful life. The landlords for each of these properties have granted us certain leasehold improvement allowances, which will reduce rent expense over the initial lease term.

#### ***Purchase Obligations***

We have committed to make future minimum payments to third parties for certain inventories and research and development supplies. The minimum contractual purchase commitments total \$11.2 million and are primarily due within 1 year.

#### **8. Collaboration, Development and Licensing Agreements**

We have entered into various collaborative agreements which provide us with rights to develop, produce and market products using certain know-how, technology and patent rights maintained by our collaborative partners. Terms of the various collaboration agreements may require us to make or receive milestone payments upon the achievement of certain product research and development objectives and pay or receive royalties on future sales, if any, of commercial products resulting from the collaboration.

Milestone payments and up-front payments received are generally reflected as revenue as discussed above in Note 1, and milestone payments and up-front payments made are generally recorded as research and development expenses if the payments relate to products that have not yet been commercialized. Milestone

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payments and up-front payments made related to commercialized tests will generally be capitalized and amortized to cost of goods sold over the economic life of the product. Royalties received will generally be reflected as product sales and services revenues and royalties paid are generally reflected as cost of goods sold.

***Illumina***

In July 2011, we entered into a Sale and Supply Agreement with Illumina, Inc., or Illumina, which we amended in September 2011, pursuant to which we and our subsidiaries will purchase laboratory equipment and consumables that will be used for our fetal chromosomal detection applications, including a noninvasive test which is designed to detect an overabundance of chromosome 21 in pregnant women, a result associated with fetal Down syndrome. This agreement requires that we submit periodic binding forecasts for consumables. Beginning in 2013, in the event that we purchase less than a specified amount of consumables during any calendar year, Illumina will be relieved of certain of its obligations and representations under the agreement, including certain of Illumina's obligations with respect to pricing terms of the consumables that we purchase. Additionally, we and Illumina have agreed to work collaboratively toward our submission for regulatory approval of an in vitro diagnostic product for the detection of fetal chromosomal abnormalities. This agreement will remain valid for a three-year term, unless terminated earlier as provided for in the agreement. Either party may terminate the agreement prior to expiration for the uncured material breach of the agreement by the other party or upon the bankruptcy or insolvency of the other party.

***CUHK***

In May 2011, we entered into a License Agreement with the Chinese University of Hong Kong, or CUHK, pursuant to which CUHK granted us an exclusive, worldwide (excluding Hong Kong), royalty-bearing license to use and to sublicense certain intellectual property covered by patent applications owned by CUHK for prenatal diagnostics, prognostics, and analysis for research and commercial purposes. This license agreement covers intellectual property rights relating to size-based genomic analysis. Pursuant to this license agreement we paid an upfront license fee to CUHK of \$1,500,000 and are obligated to pay an additional \$1,500,000 within one year. As we have determined the technology to still be in the research and development phase and has no alternative future uses, we recorded the upfront license fee of \$3.0 million as research and development expense in the second quarter of 2011. We are obligated to pay royalties on sales of products incorporating the licensed intellectual property and amounts we receive from any sublicensees. We are also obligated to pay additional amounts to CUHK upon the accomplishment of certain development and commercialization milestones. If we fail to achieve certain development and commercialization milestones within specified timeframes, CUHK may terminate this license agreement. In accordance with this license agreement, CUHK will prosecute, defend and maintain certain patent applications relating to the licensed intellectual property at our expense. This license agreement will expire on the later of 20 years or the expiration of the last patent, if any patent is issued, relating to the licensed intellectual property, unless terminated earlier pursuant to the terms of this license agreement. We may terminate this license agreement at any time after one year on 30 days written notice to CUHK. Also pursuant to this license agreement, we issued to The Chinese University of Hong Kong Foundation Limited (an affiliate of CUHK) the warrant discussed in Note 11.

Additionally, in May 2011, we entered into a four year sponsored research agreement with CUHK pursuant to which we will provide \$2.1 million of funding over the term of the agreement to CUHK for performing certain research projects that are of mutual interest and benefit to us and CUHK. In conjunction with this agreement, CUHK granted to us certain license and license option rights. We are amortizing each annual funding payment to research and development expense on a straight-line basis.

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**ISIS**

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 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.

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.

**9. Litigation**

*Patent Litigation*

On December 19, 2011, we were named as a defendant in a complaint filed by plaintiff Aria Diagnostics, Inc. (Aria) in the United States District Court for the Northern District of California. In the complaint, the plaintiff seeks a judicial declaration that no activities related to the plaintiff's non-invasive, prenatal test using cell-free DNA circulating in the blood of a pregnant woman do or will infringe any claim of U.S Patent No. 6,258,540 entitled *Non-Invasive Prenatal Diagnosis* (the '540 Patent), which we have exclusively in-licensed from Isis Innovation Limited (Isis). We intend to vigorously defend against the judicial declaration sought in the complaint. On January 24, 2012, we filed a complaint against defendant Aria in the United States District Court for the Southern District of California (the Aria Complaint). The Aria Complaint also names Isis as a nominal defendant for purposes of subject matter jurisdiction only and it seeks to realign Isis as a plaintiff in the matter. In the Aria Complaint, we have alleged that Aria is directly infringing the '540 Patent. We contend that the complaint filed by Aria is not a proper declaratory judgment action and should be dismissed in favor of the Aria Complaint.

On January 6, 2012, we were named as a defendant in a complaint filed by plaintiff Natera, a Delaware corporation, in the United States District Court for the Northern District of California. In the complaint, the plaintiff seeks a judicial declaration that (i) activities related to the plaintiff's non-invasive, prenatal paternity test do not directly or indirectly infringe any claim of the '540 Patent, which we have exclusively in-licensed from Isis, and (ii) one or more claims of the '540 Patent are invalid for failure to comply with the requirements of the patent laws of the United States. We intend to vigorously defend against the judicial declarations sought in the complaint. On January 24, 2012, we filed a complaint against defendants Natera and DNA Diagnostics Center, Inc. (DDC) in the United States District Court for the Southern District of California (the Natera Complaint). The Natera Complaint also names Isis as a nominal defendant for purposes of subject matter jurisdiction only and it seeks to realign Isis as a plaintiff in the matter. In the Natera Complaint, we have alleged that Natera and DDC are directly infringing the '540 Patent. As was described in our Current Report on Form

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8-K filed with the Securities and Exchange Commission on January 11, 2012, Natera filed a complaint in the United States District Court for the Northern District of California seeking a declaratory judgment that it does not infringe the '540 Patent. We contend that the complaint filed by Natera is not a proper declaratory judgment action and should be dismissed in favor of the Natera Complaint.

On February 22, 2012, we and our wholly-owned subsidiary Sequenom Center for Molecular Medicine, LLC (Sequenom CMM) were named as defendants in a complaint filed by plaintiffs Verinata Health, Inc. (Verinata) and The Board of Trustees of the Leland Stanford Junior University (Stanford) in the United States District Court for the Northern District of California. In the complaint (i) Verinata seeks a judicial declaration that activities related to its non-invasive prenatal test using cell-free DNA circulating in the blood of a pregnant woman do not directly or indirectly infringe any claim of the '540 Patent, which we have exclusively in-licensed from Isis, (ii) Verinata seeks a judicial declaration that each claim of the '540 Patent is invalid for failure to comply with the requirements of the patent laws of the United States, and (iii) Verinata and Stanford allege that we and Sequenom CMM, by performing its non-invasive prenatal MaterniT21™ laboratory-developed test (LDT), have and continue to directly infringe U.S. Patent No. 8,008,018 entitled *Determination of Fetal Aneuploidies by Massively Parallel DNA Sequencing* and U.S. Patent No. 7,888,017 entitled *Non-invasive Fetal Genetic Screening by Digital Analysis*, each of which have been exclusively licensed to Verinata by Stanford. We intend to vigorously defend against the judicial declarations sought and allegations of infringement set forth in the complaint.

On February 29, 2012, we and our wholly-owned subsidiary Sequenom CMM were named as defendants in a complaint filed by plaintiffs ArcticDx, Inc. (ArcticDx), ArcticAx, Inc. (ArcticAx), and ArcticAx US Ltd. (together with ArcticDx and ArcticAx, collectively referred to as Arctic) in the United States District Court for the Eastern District of Texas. In the complaint (i) ArcticDx alleges that we and Sequenom CMM, by performing its RetnaGene AMD LDT to predict genetic predisposition to late-stage (wet) age-related macular degeneration (AMD), have and continue to directly infringe U.S. Patent No. 8,114,592, which ArcticDx has exclusively licensed from the Cambridge Enterprise Limited, (ii) Arctic seeks a judicial declaration that activities related to its Macula Risk genetic test for the indication of individuals with AMD do not directly or indirectly infringe any claim of U.S. Patent No. 8,053,190 (the '190 Patent), U.S. Patent No. 7,867,727 (the '727 Patent), U.S. Patent No. 7,695,909 (the '909 Patent), U.S. Patent No. 7,351,524 (the '524 Patent), and U.S. Patent No. 8,088,579 (the '579 Patent), all of which we have exclusively in-licensed from Ophtherion, Inc., and (iii) Arctic seeks a judicial declaration that the claims of the '190 Patent, the '727 Patent, the '909 Patent, the '524 Patent, and the '579 Patent are invalid for failure to comply with the requirements of the patent laws of the United States. We intend to vigorously defend against the judicial declarations sought and allegations of infringement set forth in the complaint.

***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).

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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.

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 October 2009, the District Court certified the settlement class in each IPO Case and granted final approval to the settlement. Thereafter, a number of shareholders filed appeals to the Second Circuit, objecting to the settlement. On January 10, 2012, the last of these shareholder appeals was dismissed with prejudice. Accordingly, the settlement is now final, all claims against us and our officers and directors in the IPO Cases will be dismissed 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 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

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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.

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 complaint, *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 had initiated an investigation following our April 2009 announcement regarding the trisomy 21 test then under development. As part of this investigation, the SEC staff 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 was 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.

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On September 1, 2011, the SEC, pursuant to Section 21C of the Exchange Act, entered a cease-and-desist Order against us relating to our public statements made between June 2008 and January 2009 regarding our trisomy 21 test then under development. In accordance with the cease-and-desist Order, we have agreed not to commit or to cause any future violations of Sections 10(b) and 13(a) of the Exchange Act, and Rules 10b-5, 12b-20, 13a-1, and 13a-11 promulgated thereunder, and monetary penalties were not imposed against us.

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. Prior to sentencing, Dr. Dragon passed away in February 2011.

***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 have cooperated 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.

***Former Employee 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.

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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. At this time an estimate cannot reasonably be made regarding the possible loss or range of loss in connection with this matter. The appeal is currently pending.

In addition, from time to time, we may be involved in litigation 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.

#### **10. 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 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 purchased by Boston University totaling \$34,000, \$17,000, and \$141,000, in the years ended December 31, 2011, 2010, and 2009, respectively. We have agreements with Boston University in which Dr. Cantor participates that we paid \$204,000, \$214,000, and \$393,000 in the years ended December 31, 2011, 2010, and 2009, respectively.
- University of California, San Diego (UCSD). Dr. Cantor is adjunct professor in the department of bioengineering and Dr. Allan Bombard is our Chief Medical Officer and a clinical professor in the department of reproductive medicine at UCSD. We recorded product revenue for MassARRAY hardware and consumables purchased by UCSD totaling \$4,000, \$187,000, and \$3,300 in the years ended December 31, 2011, 2010, and 2009, respectively. We have agreements with UCSD on which we paid \$0, \$0, and \$56,600 in the years ended December 31, 2011, 2010, and 2009, 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, 2011, 2010, and 2009, we have recorded product revenue for MassARRAY hardware and consumables purchased by Scripps totaling approximately \$42,000, \$86,000, and \$35,200, respectively. We have agreements with Scripps on which we paid \$0, \$1,500, and \$61,300 in the years ended December 31, 2011, 2010, and 2009, respectively.

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- Albert Einstein College of Medicine. Dr. Bombard is clinical professor, obstetrics and gynecology, Albert Einstein College of Medicine. For the years ended December 31, 2011, 2010, and 2009, we have recorded product revenue for MassARRAY hardware and consumables purchased by the Albert Einstein College of Medicine totaling approximately \$98,000, \$89,000, and \$0, respectively.

At December 31, 2011, we had the following receivable and payable balances with the following related parties (in thousands):

<u>Related party</u>	<u>Receivables</u>	<u>Payables</u>
Boston University	\$ 10	\$ 27
Scripps	8	—
UCSD	3	—
Albert Einstein College of Medicine	24	—
<b>Total</b>	<b>\$ 45</b>	<b>\$ 27</b>

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

<u>Related party</u>	<u>Receivables</u>	<u>Payables</u>
Boston University	\$ 6	\$ 51
Scripps	20	—
UCSD	5	—
Albert Einstein College of Medicine	8	—
<b>Total</b>	<b>\$ 39</b>	<b>\$ 51</b>

## 11. Stockholders' Equity

In May 2011, pursuant to a license agreement, we issued to The Chinese University of Hong Kong Foundation Limited (an affiliate of CUHK) a warrant to purchase up to 200,000 shares of our common stock at a price of \$7.00 per share, the closing price of our common stock at the time of issuance of the warrant. The warrant was immediately exercisable, in whole or in part, but not for less than 20,000 shares and in increments of 20,000 shares, has a term of seven years, and was valued at \$1.2 million using the Black-Scholes pricing model, which we recorded as research and development expense in 2011.

In December 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*.

In December 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.

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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***

In May 2006, our stockholders approved our 2006 equity incentive plan (the 2006 plan), as the successor to our 1999 stock option plan (the 1999 plan). The aggregate number of shares of common stock that may be issued under the 2006 plan is 13,321,548, and includes 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-Based Compensation Expense***

The estimated fair value of each stock option award granted and for stock purchased under the ESPP was determined on the date of grant using the Black-Scholes option pricing model with the following assumptions during the years ended December 31:

***Stock options***

	2011	2010	2009
Risk free interest rate	2.16% - 2.53%	2.62% - 3.05%	2.72% - 2.94%
Volatility	95.6% - 99.4%	99.7% - 101.1%	87.6% - 100.7%
Dividend yield	0%	0%	0%
Expected option life (years)	7.5 -7.6	7.3 -7.5	7.0
Weighted average fair value	\$ 5.74	\$ 4.99	\$ 11.17

***ESPP***

	2011	2010	2009
Risk free interest rate	0.1%	0.2%	0.3%
Volatility	61.5%	42.4%	121.0%
Dividend yield	0%	0%	0%
Expected option life (years)	0.5	0.5	0.5
Weighted average fair value	\$ 1.03	\$ 0.42	\$ 1.91

Our determination of fair value is affected by our stock price as well as assumptions regarding a number of complex and subjective variables that require judgment. The risk-free interest rate assumption is based on 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

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the expected option life assumption is based on a weighted-average calculation combining the average historical exercise activity and assumptions regarding the estimated life of all unexercised, outstanding stock options and stock purchased under the ESPP.

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 11.2% based on historical experience. Changes in forfeiture estimates impact compensation cost in the period in which the change in estimate occurs.

***Stock Options***

A summary of the combined activity under our stock option plans 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, 2008	6,238,071	\$ 7.70		
Granted	2,263,091	\$ 14.09		
Forfeitures and cancelled	(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		
Forfeitures and cancelled	(574,136)	\$ 25.27		
Exercised	(1,036,165)	\$ 2.52		
Outstanding at December 31, 2010	6,153,422	\$ 8.33		
Granted	2,643,994	\$ 6.76		
Forfeitures and cancelled	(697,168)	\$ 13.52		
Exercised	(253,835)	\$ 3.85		
Outstanding at December 31, 2011	<u>7,846,413</u>	<u>\$ 7.49</u>	<u>7.2</u>	<u>\$2,157,868</u>
Options vested and exercisable at December 31, 2011	<u>4,833,075</u>	<u>\$ 7.45</u>	<u>6.3</u>	<u>\$2,099,467</u>

The aggregate intrinsic value of stock options exercised in 2011, 2010, and 2009 was \$673,000, \$4.3 million and \$1.6 million, respectively. As of December 31, 2011, there was \$15.8 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 2.7 years. Cash received from stock option exercises for the years ended December 31, 2011 and 2010 was \$977,000 and \$2.6 million, respectively. At December 31, 2011, there were 5,053,262 shares available for future option grants.

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**Restricted Stock**

Restricted stock units are generally performance based awards, and vest upon achievement of defined performance targets. The following table summarizes activity related to our restricted stock units and awards:

	<u>Number of Shares</u>	<u>Weighted Average Grant Date Fair Value</u>
Restricted Stock - December 31, 2008	143,376	\$ 12.19
Grants and awards	1,287,813	\$ 8.13
Vested and released	(23,977)	\$ 16.08
Forfeitures and cancelled	<u>(78,661)</u>	<u>\$ 16.58</u>
Restricted stock - December 31, 2009	1,328,551	\$ 8.88
Grants and awards	32,962	\$ 5.20
Vested and released	(80,937)	\$ 4.83
Forfeitures and cancelled	<u>(137,025)</u>	<u>\$ 3.86</u>
Restricted stock - December 31, 2010	1,143,551	\$ 4.29
Grants and awards	237,784	\$ 6.91
Vested and released	(107,191)	\$ 7.14
Forfeitures and cancelled	<u>(299,204)</u>	<u>\$ 4.12</u>
Restricted stock - December 31, 2011	<u>974,940</u>	<u>\$ 4.65</u>

The fair value of restricted stock that vested was \$647,000, \$332,000, and \$1.0 million in 2011, 2010, and 2009, respectively.

**Employee Stock Purchase Plan**

In 1999, we adopted the 1999 Employee Stock Purchase Plan (the 1999 ESPP). As of December 31, 2011, we had reserved 747,621 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, 2011, employees have contributed approximately \$509,000 to the current offering of the 1999 ESPP since the beginning of the offering period that commenced August 1, 2011. For the years ended December 31, 2011, 2010 and 2009, we recognized approximately \$466,000, \$352,000, and \$243,000, respectively, as stock-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 550,000 shares of common stock, as amended. 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

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former employees or directors unless there has been a bona fide period of non-employment. As of December 31, 2011, 224,200 equity awards had been issued under the New-Hire Plan.

***Warrants***

In May 2011, pursuant to a license agreement, we issued to The Chinese University of Hong Kong Foundation Limited (an affiliate of CUHK) a warrant to purchase up to 200,000 shares of our common stock at a price of \$7.00 per share, the closing price of our common stock at the time of issuance of the warrant. The warrant was immediately exercisable, in whole or in part, but not for less than 20,000 shares and in increments of 20,000 shares, has a term of seven years, and was valued at \$1.2 million using the Black-Scholes pricing model, which we recorded as research and development expense in 2011.

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. The option to purchase the remaining shares related to this warrant expired as of December 31, 2011 without being exercised.

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, 2011, the warrant had not been exercised and expires in October 2015.

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. The option to purchase the shares related to this warrant expired as of December 31, 2011 without being exercised.

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**December 31, 2011**

**12. Income Taxes**

We recognize 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.

Following is a tabular reconciliation of the Unrecognized Tax Benefit, or UTB activity for the two years ended December 31, 2011 (excluding interest and penalties, 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 statute of limitations	—
Ending balance, December 31, 2010	<u>\$1,660</u>
Additions based on tax positions related to the prior year	—
Additions based on tax positions related to the current year	873
Reductions for tax positions of prior year	—
Settlements	—
Reductions due to lapse of applicable statute of limitations	—
Ending balance, December 31, 2011	<u>\$ 2,533</u>

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, 2011 and 2010 and have recognized no interest and/or penalties in the statement of operations for the year ended December 31, 2011.

We are subject to taxation in the U.S., foreign and various state jurisdictions. Our tax years for 1996 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. Included in the UTB is \$548,000 that if recognized would impact our effective tax rate. Due to the existence of the valuation allowance, future changes in the other unrecognized tax benefits will not impact our effective tax rate. We anticipate that some of the UTB will be decreased with an impact to the effective tax rate in the next twelve months. At this time we cannot estimate what this amount will be.

**SEQUENOM, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2011**

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,		
	2011	2010	2009
Tax at statutory rate	\$(25,921)	\$(42,299)	\$(24,805)
State taxes, net of federal benefit	(2,850)	(5,365)	(2,910)
Change in valuation allowance	3,332	125	(30,458)
Federal and state NOL limitations	25,394	45,556	49,045
Change in state rate	305	(134)	3,724
Credits and other	(165)	2,107	5,521
	<u>\$ 95</u>	<u>\$ (10)</u>	<u>\$ 117</u>

The 2011 income tax expense of \$95,000 and 2010 income tax benefit of \$10,000 are primarily 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,	
	2011	2010
Deferred tax assets:		
Foreign net operating loss carryforwards	\$ 2,697	\$ 2,679
Capitalized research expenses	6,213	6,888
Depreciation	1,080	1,107
Stock options	7,010	5,012
Accruals and reserves	8,123	6,623
Other, net	674	216
Total deferred tax assets	<u>25,797</u>	<u>22,525</u>
Valuation allowance	<u>(25,797)</u>	<u>(22,525)</u>
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

At December 31, 2011, we had federal and state tax net operating loss carryforwards of approximately \$304.8 million and \$249.1 million, respectively. The federal and state net operating losses have been reduced by the Section 382 limitation analysis completed in 2008. 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 \$5.0 million and \$12.4 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.

**SEQUENOM, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2011**

**13. 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 2011, 2010, and 2009.

**14. 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. We had revenues in the following countries or regions for the years ended December 31, 2011, 2010 and 2009 (in thousands):

	<u>December 31,</u>		
	<u>2011</u>	<u>2010</u>	<u>2009</u>
Revenues:			
United States	\$ 27,047	\$21,891	\$18,017
China	6,056	4,037	1,723
Japan	2,406	2,678	2,409
Australia	2,267	1,937	1,830
Other Asia	4,277	3,795	2,731
Germany	2,684	2,740	3,036
United Kingdom	2,635	3,381	2,451
Other Europe	8,535	7,000	5,666
	<u>\$55,907</u>	<u>\$47,459</u>	<u>\$37,863</u>

For individual country or geographical revenue reporting, revenues are attributed to the individual country or geographic location in which the product is shipped. There were no material amounts of transfers between geographic areas.

Net long-lived assets exclude goodwill and other intangible assets since they are not allocated on a geographic basis. The Company had net long-lived assets consisting of property and equipment in the following regions as of December 31, 2011 and 2010 (in thousands):

	<u>December 31,</u>	
	<u>2011</u>	<u>2010</u>
United States	\$ 19,122	\$10,596
Europe	273	288
Asia	234	154
	<u>\$19,629</u>	<u>\$ 11,038</u>

**SEQUENOM, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2011**

**16. Selected Quarterly Financial Data (unaudited)**

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total Year
(In thousands, except share and per share information)					
<b>2011</b>					
Total Revenues	\$ 13,510	\$ 13,332	\$ 13,581	\$ 15,484	\$ 55,907
Gross margin	8,497	8,907	8,122	7,067	32,593
Net loss	(12,670)	(20,938)	(18,372)	(22,177)	(74,157)
Net loss per share, basic and fully diluted	\$ (0.13)	\$ (0.21)	\$ (0.19)	\$ (0.22)	\$ (0.75)
Shares used in calculated per share amounts, historical, basic and fully diluted	98,929	99,083	99,220	99,325	99,143
<b>2010</b>					
Total Revenues	\$ 10,610	\$ 11,412	\$ 11,684	\$ 13,753	\$ 47,459
Gross margin	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

**17. Subsequent Event**

On January 25, 2012, we closed an underwritten public offering of our common stock totaling 14,950,000 shares of our common stock at \$4.15 per share. The offering resulted in aggregate net proceeds of approximately \$58.2 million after deducting underwriting commissions and transaction expenses.

**Schedule II—SEQUENOM, INC.**  
**Valuation and Qualifying Accounts**  
**(In thousands)**

<u>Description</u>	<u>Balance at Beginning of Period</u>	<u>Charged to Costs and Expenses</u>	<u>Deductions</u>	<u>Balance at End of Period</u>
<b>Year ended December 31, 2011:</b>				
Allowance for doubtful accounts	\$ 1,152	21	402	\$ 771
Reserve for obsolete or excess inventory	\$ 1,003	1,345	514 <sup>(1)</sup>	\$ 1,834
<b>Year ended December 31, 2010:</b>				
Allowance for doubtful accounts	\$ 241	923	12	\$ 1,152
Reserve for obsolete or excess inventory	\$ 1,504	141	642 <sup>(1)</sup>	\$ 1,003
<b>Year ended December 31, 2009:</b>				
Allowance for doubtful accounts	\$ 405	(145)	19	\$ 241
Reserve for obsolete or excess inventory	\$ 1,473	2,488	2,457 <sup>(1)</sup>	\$ 1,504

(1) Write off of obsolete or excess inventory

**\*\*\*Text Omitted and Filed Separately with the Securities and Exchange Commission.  
Confidential Treatment Requested Under  
17 C.F.R. Sections 200.80(b)(4) and 240.24b-2**

**First Amendment to Sale and Supply Agreement**

Sequenom, Inc. (“SQNM”) and Illumina, Inc. (“Illumina”) entered into that certain Sale and Supply Agreement with an effective date of July 8, 2011 (the “Agreement”). SQNM and Illumina desire to amend certain terms of the Agreement pursuant to the terms of this First Amendment to Sale and Supply Agreement (the “Amendment”).

By signing where indicated below, SQNM and Illumina hereby agree to amend the terms of the Agreement as follows:

1. Paragraph 8 of the Agreement is amended by deleting it in its entirety and replacing it with the following:

“8. Initial Instruments. Illumina shall ship and Customer shall take receipt of [...\*\*\*...] and [...\*\*\*...] by the end of [...\*\*\*...] and [...\*\*\*...] by [...\*\*\*...].”

2. Paragraph 7(a) is amended by changing the date [...\*\*\*...] found in the first sentence to [...\*\*\*...] and adding the following after the first sentence:

“Notwithstanding the preceding sentence, with respect to the [...\*\*\*...],[...\*\*\*...] of these kits that make up the [...\*\*\*...] samples worth of [...\*\*\*...] Consumables shall be received by [...\*\*\*...] and the remaining [...\*\*\*...] shall be received by [...\*\*\*...]. The preceding does not apply to any other of the kits that comprise [...\*\*\*...] Consumables.”

3. Paragraph 7(b) is amended by deleting it in its entirety and replacing it with the following:

“b. [...\*\*\*...] **samples.** Illumina shall ship and Customer shall take receipt of an additional [...\*\*\*...] samples worth of [...\*\*\*...] Consumables, as detailed by specific kits in Appendix I, by [...\*\*\*...]. Notwithstanding the preceding sentence, with respect to the [...\*\*\*...], half of these kits that make up the [...\*\*\*...] samples worth of [...\*\*\*...] Consumables shall be received by the Customer by [...\*\*\*...] and the remaining half shall be received by [...\*\*\*...]. The preceding does not apply to any other of the kits that comprise [...\*\*\*...] Consumables. Except for the [...\*\*\*...], these [...\*\*\*...] Consumables will be manufactured in a single lot per kit type and shipped to Customer in a single lot per kit type. Customer shall [...\*\*\*...] of the purchase price of these [...\*\*\*...] samples worth of [...\*\*\*...] Consumables plus pay [...\*\*\*...], for which Illumina shall invoice Customer after [...\*\*\*...]. Illumina shall invoice Customer for such [...\*\*\*...] Consumables pursuant to the invoicing terms of this Agreement.”

4. The last line of Paragraph 7 (c) is amended by deleting it in its entirety and replacing it with the following:

“Except for the [...\*\*\*...], which will have no less than [...\*\*\*...] shelf life at the time of shipment, all [...\*\*\*...] Consumables ordered under this Section 7 shall have no less than [...\*\*\*...] shelf life at the time of shipment.”

5. Except as expressly modified herein, the Agreement shall remain in full force and effect in accordance with its terms.

\*\*\*Confidential Treatment Requested

**CONFIDENTIAL**

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**IN WITNESS WHEREOF**, the parties have signed this Amendment as of the dates indicated below.

**ILLUMINA**

By: /s/ Nicholas Naclerio  
Name: Nicholas Naclerio  
Title: Sr. VP, Corporate & Venture Development  
Date: 9/29/2011

**SEQUENOM**

By: /s/ Harry F. Hixson Jr.  
Name: Harry F. Hixson Jr., Ph.D.  
Title: Chief Executive Officer  
Date: 9/27/2011

## SUBSIDIARIES OF THE REGISTRANT

Sequenom—Gemini, Ltd.	England and Wales
Gemini Genomics, (UK) Ltd.	England and Wales
Gemini Genomics, Ltd.	England and Wales
Sequenom GmbH	Germany
Sequenom K.K.	Japan
Sequenom Hong Kong, Ltd	Hong Kong
Sequenom Biosciences (India) Pvt. Ltd	India
Sequenom Center for Molecular Medicine, LLC	United States

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-172302, 333-167831, 333-152230, 333-134906, 333-125456, 333-112322, 333-102769, 333-99629, 333-90778 and 333-67332) and Form S-3 (Nos. 333-178134, 333-169513 and 333-167061) of Sequenom, Inc. and in the related Prospectuses of our reports dated March 9, 2012, with respect to the consolidated financial statements and schedule of Sequenom, Inc., and the effectiveness of internal control over financial reporting of Sequenom, Inc., included in this Annual Report (Form 10-K) for the year ended December 31, 2011.

/s/ Ernst & Young LLP

San Diego, California

March 9, 2012

## CERTIFICATION

I, Harry F. Hixson, Jr., certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2011 of Sequenom, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 9, 2012

/s/ HARRY F. HIXSON, JR.

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Harry F. Hixson, Jr.  
Chief Executive Officer  
(Principal Executive Officer)

## CERTIFICATION

I, Paul V. Maier, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2011 of Sequenom, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 9, 2012

/s/ PAUL V. MAIER

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Paul V. Maier  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. § 1350), Harry F. Hixson Jr., Chief Executive Officer of Sequenom, Inc. (the "Company"), hereby certify that, to the best of his knowledge:

1. The Company's Annual Report on Form 10-K for the period ended December 31, 2011, to which this Certification is attached as Exhibit 32.1 (the "Annual Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act, and
2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission ("SEC") or its staff upon request.

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the SEC and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Annual Report), irrespective of any general incorporation language contained in such filing.

**IN WITNESS WHEREOF**, the undersigned has set his hand hereto as of the 9th day of March, 2012.

/S/ HARRY F. HIXSON JR.

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Harry F. Hixson Jr.  
Chief Executive Officer  
(Principal Executive Officer)

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. § 1350), Paul V. Maier, Principal Financial and Accounting Officer of Sequenom, Inc. (the "Company"), hereby certifies that, to the best of his knowledge:

1. The Company's Annual Report on Form 10-K for the period ended December 31, 2011, to which this Certification is attached as Exhibit 32.1 (the "Annual Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act, and
2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission ("SEC") or its staff upon request.

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the SEC and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Annual Report), irrespective of any general incorporation language contained in such filing.

**IN WITNESS WHEREOF**, the undersigned has set his hand hereto as of the 9th day of March, 2012.

/S/ PAUL V. MAIER

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**Paul V. Maier**  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

