

ORIGINAL

FILED

09 MAY -1 AM 10:00

CLERK, U.S. DISTRICT COURT  
SOUTHERN DISTRICT OF CALIFORNIA

BY:

DEPUTY

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF CALIFORNIA

██████████ Individually and on Behalf )  
of All Others Similarly Situated, )

Plaintiff, )

vs. )

SEQUENOM, INC., HARRY STYLLI, PAUL )  
W. HAWRAN, ALLAN BOMBARD, )  
CHARLES R. CANTOR and ELIZABETH )  
DRAGON, )

Defendants. )

No. 09 CV 921 BTM

WMC

CLASS ACTION

COMPLAINT FOR VIOLATION OF THE  
FEDERAL SECURITIES LAWS

DEMAND FOR JURY TRIAL

*ck*

## INTRODUCTION

1  
2 1. This is a securities class action on behalf of all persons who purchased or otherwise  
3 acquired the common stock of Sequenom, Inc. between June 4, 2008 and April 29, 2009, inclusive  
4 (the "Class Period"), against Sequenom and certain of its officers and/or directors for violations of  
5 the Securities Exchange Act of 1934 (the "1934 Act").

6 2. Sequenom is a diagnostic testing and genetics analysis company. The Company is  
7 researching, developing and pursuing the commercialization of various non-invasive molecular  
8 diagnostic tests for prenatal genetic disorders and diseases, oncology, infectious diseases, and other  
9 diseases and disorders.

10 3. During the Class Period, defendants issued materially false and misleading statements  
11 regarding the Company's Down syndrome test under development. Specifically, defendants failed  
12 to disclose that Sequenom employees mishandled test data and results regarding the Down syndrome  
13 test. As a result of defendants' false and misleading statements, Sequenom stock traded at  
14 artificially inflated prices during the Class Period, reaching a high of \$27.76 per share on September  
15 24, 2008. This inflated stock price permitted Sequenom to raise \$92 million in a secondary stock  
16 offering in July 2008, acquire a diagnostic company for fewer shares of Sequenom stock than would  
17 have been necessary absent the inflation, and commence a tender offer for another company in an  
18 all-stock transaction.

19 4. On April 29, 2009, after the market closed, the Company issued a press release  
20 entitled "Sequenom Announces Delay in Launch of SEQuereDx Trisomy 21 Test." The press release  
21 stated in part:

22 Sequenom, Inc. announced today that the expected launch of its SEQuereDx™ Down  
23 syndrome test is delayed, due to the discovery by company officials of employee  
24 mishandling of R&D test data and results. Accordingly the company is no longer  
25 relying on the previously announced R&D test data and results. SEQUENOM has  
26 not changed its plans to develop in parallel its RNA- and DNA-based methods for the  
27 Down syndrome test and will endeavor to have a validated test in the fourth quarter  
of 2009. Under the circumstances, and as supported by key clinical opinion leaders,  
the company now intends to launch the Down syndrome test upon publication in a  
peer-reviewed journal of the results from the on-going large, independent clinical  
studies, which are designed to be practice-changing for Down syndrome testing.

28 The company's board of directors has formed a special committee of  
independent directors to oversee an independent investigation of the employees'

1 activity related to the test data and results. The committee has engaged independent  
2 counsel to assist the committee in the conduct of the investigation.

3 \* \* \*

4 Today's announcement regarding the company's SEQuReDx Down syndrome  
5 R&D test data and results supersedes all previous announcements about such data  
6 and test, including its press releases dated June 4, 2008, September 23, 2008,  
7 December 1, 2008, January 28, 2009 and February 3, 2009.

8 5. As a result of defendants' false statements, Sequenom's stock price traded at inflated  
9 levels during the Class Period. On this news, Sequenom's stock collapsed over \$11 per share to as  
10 low as \$3.23 per share, a one-day decline of more than 75%, on volume of more than 85 million  
11 shares as artificial inflation came out of the stock price.

#### 12 JURISDICTION AND VENUE

13 6. Jurisdiction is conferred by §27 of the 1934 Act. The claims asserted herein arise  
14 under §§10(b) and 20(a) of the 1934 Act and SEC Rule 10b-5.

15 7. Venue is proper in this District pursuant to §27 of the 1934 Act. Many of the false  
16 and misleading statements were made in or issued from this District.

17 8. Sequenom's principal executive offices are located at 3595 John Hopkins Court, San  
18 Diego, California.

#### 19 PARTIES

20 9. Plaintiff [REDACTED] purchased Sequenom common stock as described in the  
21 attached certification and was damaged thereby.

22 10. Defendant Sequenom is a diagnostic testing and genetics analysis company. The  
23 Company is focused on providing products, services, diagnostic testing, applications and genetic  
24 analysis products that translate the results of genomic science into solutions for biomedical research,  
25 translational research, molecular medicine applications, and agricultural, livestock and other areas of  
26 research. Sequenom is researching, developing and pursuing the commercialization of various non-  
27 invasive molecular diagnostic tests for prenatal genetic disorders and diseases, oncology, infectious  
28 diseases, and other diseases and disorders. Sequenom is headquartered in San Diego, California.

11. Defendant Harry Stylli ("Stylli") is, and at all relevant times was, President and Chief  
Executive Officer ("CEO") and a director of Sequenom.

1           12. Defendant Paul W. Hawran ("Hawran") is, and at all relevant times was, Chief  
2 Financial Officer ("CFO") of Sequenom.

3           13. Defendant Allan Bombard ("Bombard") is, and at all relevant times was, Chief  
4 Medical Officer of Sequenom.

5           14. Defendant Charles R. Cantor ("Cantor") is, and at all relevant times was, Chief  
6 Scientific Officer of Sequenom.

7           15. Defendant Elizabeth Dragon ("Dragon") is, and at all relevant times was, Senior Vice  
8 President, Research and Development of Sequenom.

9           16. Defendants Stylli, Hawran, Bombard, Cantor and Dragon (the "Individual  
10 Defendants"), because of their positions with the Company, possessed the power and authority to  
11 control the contents of Sequenom's quarterly reports, press releases and presentations to securities  
12 analysts, money and portfolio managers and institutional investors, *i.e.*, the market. They were  
13 provided with copies of the Company's reports and press releases alleged herein to be misleading  
14 prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or  
15 cause them to be corrected. Because of their positions with the Company, and their access to  
16 material non-public information available to them but not to the public, the Individual Defendants  
17 knew that the adverse facts specified herein had not been disclosed to and were being concealed  
18 from the public and that the positive representations being made were then materially false and  
19 misleading. The Individual Defendants are liable for the false statements pleaded herein.

20                           **FRAUDULENT SCHEME AND COURSE OF BUSINESS**

21           17. Defendants are liable for: (i) making false statements; or (ii) failing to disclose  
22 adverse facts known to them about Sequenom. Defendants' fraudulent scheme and course of  
23 business that operated as a fraud or deceit on purchasers of Sequenom common stock was a success,  
24 as it: (i) deceived the investing public regarding Sequenom's prospects and business; (ii) artificially  
25 inflated the price of Sequenom's common stock; and (iii) caused plaintiff and other members of the  
26 Class to purchase Sequenom common stock at inflated prices.

27  
28

1 **BACKGROUND**

2 18. Sequenom, incorporated in 1994, is a diagnostic testing and genetics analysis  
3 company. The Company is focused on providing products, services, diagnostic testing, applications  
4 and genetic analysis products that translate the results of genomic science into solutions for  
5 biomedical research, translational research, molecular medicine applications, and agricultural,  
6 livestock and other areas of research. Its development and commercialization efforts in various  
7 diagnostic areas include non-invasive prenatal diagnostics, oncology, infectious diseases and other  
8 disorders. The Company is researching, developing and pursuing the commercialization of various  
9 non-invasive molecular diagnostic tests for prenatal genetic disorders and diseases, oncology,  
10 infectious diseases, and other diseases and disorders.

11 19. The Company was focusing on non-invasive Down syndrome screening technology  
12 as the Class Period began in what the Company termed a "\$2 billion" opportunity. This was  
13 electrifying for a company whose annual revenues were less than \$50 million.

14 **DEFENDANTS' FALSE AND MISLEADING STATEMENTS ISSUED**  
15 **DURING THE CLASS PERIOD**

16 20. On June 4, 2008, Sequenom issued a press release entitled "Sequenom Announces  
17 Results of Screening Studies for Down Syndrome and Updates Development of Noninvasive  
18 Prenatal Diagnostics at Analyst and Investor Briefing," which stated in part:

19 Sequenom, Inc., a leading provider of genetic-analysis solutions, announced positive  
20 results from screening studies using the Company's noninvasive circulating cell-free  
21 fetal (ccff) nucleic acid SEQuereDx(TM) Technology, which enables the detection of  
22 fetal aneuploidy, including Down syndrome from maternal blood. At its analyst-and-  
23 investor briefing "The Future of Noninvasive Prenatal Diagnostics" held at the  
International Society of Prenatal Diagnostics (ISPD) conference in Vancouver,  
Canada, executives were joined by a panel of leading scientists and clinicians to  
discuss study results and updates in the development of noninvasive prenatal  
diagnostics.

24 The Company reported that in blinded studies performed at Sequenom  
25 involving approximately 200 clinical samples collected both prospectively and  
26 retrospectively, its proprietary test for Down syndrome correctly identified 100% of  
27 all Down syndrome samples (i.e. sensitivity or detection rate), without any false-  
28 positive outcomes (i.e. specificity). Population coverage for the T21 test improved to  
at least 93% of the U.S. population. With currently available serum-testing options  
having detection rates between 70% to 90% and false-positive rates as high as 5%,  
SEQuereDx Technology shows promise for significant performance advantages over  
the current paradigms for prenatal screening. The Company expects to continue its  
development activities through the end of 2008, at which time the Company will

1 initiate transfer of the technology to laboratory partners. The Company plans to  
2 initiate a multi-site validation study consisting of several thousand samples in the  
3 fourth quarter this year and launch its Down syndrome test as a Laboratory  
4 Developed Test (LDT) in the U.S. in the first half 2009.

5 "We are very pleased to be reporting substantial progress toward  
6 commercializing an important test to screen for Down syndrome that can be  
7 administered as early as late in the first trimester through a simple blood draw from  
8 the mother," said Harry Stylli, Ph.D., Sequenom's President and Chief Executive  
9 Officer. "Data from our blinded screening study for the detection of fetal aneuploidy  
10 indicate that the current version of our test has identified all Down syndrome samples  
11 without any false-positive outcomes. Also our coverage has improved to at least 93%  
12 of the U.S. population. Although these results require further validation in larger  
13 studies, such results using SEQuReDx™ Technology can potentially transform  
14 current clinical practice for Down syndrome-risk assessment."

15 The studies conducted both prospectively and retrospectively, involved  
16 approximately 200 samples in both normal and high-risk patients. The blinded-  
17 prospective study involved 180 samples comprising 130 low-risk and 50 high-risk  
18 samples. The test correctly identified three Down syndrome samples without any  
19 false-positive outcomes. Of the 21 blinded samples analyzed retrospectively, the test  
20 correctly identified seven Down syndrome samples while also indicating no false-  
21 positive results.

22 "A direct, noninvasive genetic assessment of fetal Down syndrome will result  
23 in far-better screening accuracy and would dramatically reduce the number of  
24 unnecessary, invasive diagnostic procedures that women undergo in current maternal  
25 serum-screening protocols. Improved detection rates, as reported by Sequenom in its  
26 assay optimization studies, exceed those with currently available screening models,"  
27 said Allan T. Bombard, M.D., a reproductive geneticist with more than two decades  
28 of experience in the field of prenatal screening and diagnosis. (Dr. Bombard serves  
as a Chief Medical Director at Sharp Mary Birch Hospital and is the Principal  
Investigator of the study.) "Moreover, having minimum false-positive results will  
significantly reduce the number of unnecessary confirmatory diagnostic tests, as well  
as the anxiety and complications associated with invasive procedures."

Currently available tests conducted during the first or second trimester of  
pregnancy use epigenetic markers associated with the Down syndrome phenotype  
that are characterized as "surrogate" markers as they are not directly related to the  
extra Number 21 chromosome. Different combinations of markers, measured at  
different times in pregnancy, constitute the multiple-marker approach to screening.  
These tests have detection rates of 70% to 90% with approximately a 5% false-  
positive rate, while also having inconsistent population coverage or ethnicity rates.  
The SEQuReDx test uses a maternal blood sample drawn as early as the first trimester  
and identifies directly the extra Number 21 chromosome. Invasive procedures such  
as amniocentesis or chorionic villus sampling (CVS) carry risk of miscarriage and  
other risks to mother and fetus.

"Current screening methods, using multiple 'surrogate' markers, are very  
good, but are unlikely to reach diagnostic potential," said Jacob Canick, Ph.D.,  
Professor of Pathology and Laboratory Medicine at Brown University Medical  
School. "In contrast, I am optimistic that tests using multiple-fetal RNA and DNA  
markers can be developed not only for Down syndrome, but for all clinically  
important aneuploidies, and it is reasonable to expect that such direct, noninvasive  
diagnostics could be done in the first trimester of pregnancy."



1 Sequenom, Inc., a leading provider of genetic-analysis and molecular diagnostic  
2 solutions, announced additional, positive results from screening studies using the  
3 Company's noninvasive circulating cell-free fetal (ccff) nucleic acid SEQuereDx(TM)  
4 Technology, which enables the detection of fetal aneuploidy, including Down  
5 syndrome from maternal blood, at its Analyst Briefing in New York City. Among the  
6 data presented, Sequenom's test demonstrated complete concordance with clinical  
7 results (no false positives and no false negatives) in both first and second trimester  
8 samples (over 200 samples announced today and in excess of 400 prospective  
9 samples to-date). Sequenom executives were joined by a panel of leading scientists  
10 and clinicians to discuss these study results and updates in the development of  
11 noninvasive prenatal diagnostics.

12 "These data expand upon the data we announced in June and underscore the  
13 potential for our SEQuereDx Technology to transform current clinical practice for  
14 prenatal diagnostics as a primary screening tool for Trisomy 21. Furthermore, these  
15 results support the potential for our test to be used in the first trimester," said Harry  
16 Stylli, Ph.D., Sequenom's President and Chief Executive Officer. "In addition, our  
17 announcement earlier today regarding our acquisition of the Center for Molecular  
18 Medicine, a CLIA-certified molecular diagnostics laboratory, and our partnership  
19 with Spectrum Health and the Van Andel Research Institute, provides us with  
20 important infrastructure and commercialization control. We are delighted with our  
21 progress in bringing to market an important, noninvasive screening test for Down  
22 syndrome, as well as a broader menu of molecular diagnostic tests. These results are  
23 very promising, and we look forward to continuing the clinical development and  
24 validation progress to launch in the first half of 2009."

25 Elizabeth Dragon, Ph.D., Senior Vice President of Research and  
26 Development at Sequenom, presented data from blinded studies performed at  
27 Sequenom involving 219 new clinical samples collected prospectively, showing that  
28 its proprietary test for Down syndrome correctly identified 100% of all Down  
syndrome samples (i.e. sensitivity or detection rate), without any false-positive  
outcomes (i.e. specificity). The SEQuereDx prototype test also demonstrated its  
ability to correctly identify a Down syndrome positive sample in the first trimester,  
confirmed by chorionic villus sampling (CVS), a current testing standard that  
requires the harvesting of placental tissue cells.

Sequenom indicated that with the addition of new SNPs in PLAC4 and a  
recently discovered gene, the SEQuereDx Trisomy 21 test should increase its  
coverage from 93% to greater than 95% in the US population. The Company has also  
identified novel markers for Trisomy 18 that have passed its initial selection criteria,  
and other chromosomes, and intends to develop these markers into new tests.

The Company expects to continue its current development activities through  
the end of 2008, at which time the Company will initiate a multi-site 3,000 to 5,000-  
sample laboratory developed test (LDT) validation study, which is expected to be  
completed and submitted for publication at the time of the anticipated commercial  
launch in June 2009. To facilitate the LDT validation study, Sequenom also indicated  
that the company will be collaborating with new clinical partners who perform in  
excess of 12,000 amniocenteses and 3,000 CVS per year. In addition, Sequenom  
announced sponsorship of the RNA Noninvasive Aneuploidies ("RNA") study, a  
landmark, multi-center, prospective study involving up to 10,000 samples from first  
and second trimester pregnancies using the SEQuereDx technology, managed and  
analyzed by an independent third-party.



2008 Third Quarter and Recent Highlights

– Further Positive Results from Down Syndrome Screening Study: In late September Sequenom announced additional positive results from screening studies for detection of fetal aneuploidy, including Down syndrome, from maternal blood using Sequenom’s noninvasive circulating cell-free fetal (ccff) nucleic acid SEQuereDx Technology. At the Analyst and Investor Briefing, Sequenom presented data demonstrating complete concordance with clinical results (no false positives and no false negatives) in both first and second trimester samples from an additional 200 (400 in total) prospective samples.

29. On December 1, 2008, Sequenom issued a press release entitled “Next-Generation Noninvasive Diagnostic Technology Shown to Accurately Detect Fetal Down Syndrome in First Trimester of Pregnancy,” which stated in part:

Sequenom, Inc. announced new data from a collaborative project with The Chinese University of Hong Kong, published this week in the Early Edition of the Proceedings of the National Academy of Sciences, that demonstrate its innovative, next-generation, noninvasive prenatal diagnostic technology accurately quantified maternal plasma DNA sequences for fetal Trisomy 21, or Down syndrome, based on samples taken from women in the first and second trimesters of pregnancy. These data are the first to suggest that this future approach, based on massively parallel genomic DNA sequencing, can be effective in women who had not previously undergone invasive procedures.

This study used massively parallel genomic sequencing to quantify maternal plasma DNA sequences for the noninvasive prenatal detection of Down syndrome, assessing samples from 28 women in the first and second trimesters of pregnancy. All 14 Down syndrome fetuses and normal fetuses were correctly identified at these early stages.

“Current invasive methods for diagnosing Down syndrome in pregnancy have documented risks associated with such procedures. Our new study using massively parallel genomic DNA sequencing represents a ‘next-generation’ technology for noninvasive, safe testing of Down syndrome. This is the first study to show that this approach can be used for the detection of Down syndrome in both the first and second trimesters, based on a rigorously controlled clinical cohort in which the pregnant women with fetuses affected by Trisomy 21 and those with normal fetuses were matched in gestational age, and in which most of the studied subjects had not previously undergone an invasive procedure. The latter point is important as it shows that the method would truly work in the noninvasive prenatal diagnostic scenario. This study also employs a novel data analysis algorithm which has achieved an unprecedented clear separation of the Trisomy and normal samples,” stated Dennis Lo, M.D., Ph.D., co-author of the study, and Li Ka Shing, Professor of Medicine at The Chinese University of Hong Kong. “While this new approach is several years away as a commercially viable test, we believe that massively parallel genomic sequencing of DNA in maternal plasma may offer a complementary approach to the RNA SNP allelic ratio approach that we reported last year for Trisomy 21 detection. The two approaches have performance and cost profiles which would potentially be synergistic to one another.”

1           Sequenom licensed the exclusive rights to the massively parallel genomic  
2 DNA sequencing technology featured in this study from The Chinese University of  
3 Hong Kong in September 2008.

4           “Screening tests currently available for early detection of Down syndrome  
5 and other chromosomal disorders are associated with a relatively high rate of  
6 inaccuracy, which can result in an overlooked abnormality or, in the case of false  
7 positive results, unnecessary invasive and risky procedures,” stated Harry Stylli,  
8 Ph.D., President and Chief Executive Officer of Sequenom. “Systems to support  
9 DNA sequencing like massively parallel genomic sequencing or shotgun sequencing  
10 are currently limited to the academic setting due to scalability limitations and high  
11 cost, therefore practical applications are several years from commercialization. We  
12 find the data reported by Dr. Lo and associates to be very compelling and, while we  
13 continue to evaluate other promising approaches, Sequenom licensed this technology  
14 several months ago because we believe massively parallel genomic sequencing is a  
15 promising approach to prenatal diagnostics that may offer a future extension to our  
16 SEQuereDx(TM) prenatal diagnostics franchise. Even though this technology is years  
17 away from the clinic, we expect that our current RNA SNP allelic ratio technology -  
18 which is the basis for the Down syndrome test we expect to launch in June 2009 -  
19 will represent a major step forward in maternal and fetal testing.”

20           Current screening technology for Down syndrome includes serum marker  
21 analysis, such as the quad screen and first trimester combined screening that employs  
22 both serum marker testing and nuchal translucency. These approaches have detection  
23 or sensitivity rates of 80% and 85% respectively, which means between 15% and  
24 20% of all Down syndrome-affected pregnancies will not be identified as needing  
25 further evaluation. In addition, these approaches also have false positive rates  
26 between 5% and 10%, resulting in hundreds of thousands of unnecessary, highly  
27 invasive CVS or amniocentesis procedures. These invasive procedures, which are  
28 used to determine whether the fetus has Down syndrome, carry a risk of miscarriage  
in the range of one-in-100 to one-in-300.

          The study, entitled “Noninvasive prenatal diagnosis of fetal chromosomal  
aneuploidy by massively parallel genomic sequencing of DNA in maternal plasma”  
by Chiu et. al., is available online in this week’s Early Edition of PNAS at  
[www.PNAS.org](http://www.PNAS.org).

30.       On January 14, 2009, Sequenom announced that it intended to make an exchange  
offer to acquire all of the outstanding shares of common stock of EXACT Sciences Corporation in  
an all-stock transaction valued at approximately \$41 million. Under the terms of the proposal, each  
share of EXACT Sciences would be exchanged for \$1.50 in Sequenom common stock. This  
consideration would be subject to a floating exchange rate within a 15% collar, in which the price of  
Sequenom’s common stock is between \$20.74 and \$28.06 per share.

31.       On January 28, 2009, Sequenom issued a press release entitled “Sequenom Center for  
Molecular Medicine Collaborates with Obstetrix Medical Group to Provide Clinical Samples for

1 LDT Validation Study – Collaboration with Leading Maternal-Fetal Medicine Physician Group  
2 Signifies Further Step Toward Commercializing Trisomy 21 Test,” which stated in part:

3 Sequenom, Inc., today announced a collaboration with Obstetrix Medical Group, to  
4 provide the Sequenom Center for Molecular Medicine (SCMM) with samples for a  
5 study to further evaluate its novel, noninvasive prenatal test to assess Down  
6 syndrome (Trisomy 21) based on its circulating cell-free fetal (ccff) nucleic acid  
7 SEQuereDx™ technology. Obstetrix is a national physician group practice of  
8 maternal-fetal medicine specialists that is affiliated with Pediatrix Medical Group.

9 This prospective multi-center feasibility study, “Noninvasive Screening for  
10 Fetal Aneuploidy: A New Maternal Plasma Marker,” is designed as a Laboratory  
11 Developed Test (LDT) validation study and will evaluate up to 5,000 samples. To  
12 facilitate the LDT validation of the SEQuereDx Trisomy 21 Test, Sequenom will be  
13 collaborating with physicians practicing as part of Obstetrix as well as other  
14 maternal-fetal medicine practices. According to the study protocol, Obstetrix will  
15 collect clinical maternal plasma samples prior to performing an amniocentesis or  
16 chorionic villus sampling (CVS) procedure. SCMM will then compare results for the  
17 detection of Down syndrome using its prototype test of maternal blood samples to  
18 the related amniocentesis or CVS results.

19 “We are delighted to be working with Obstetrix, a highly respected leader in  
20 the care of women during high-risk pregnancies,” said Harry Stylli, Ph.D.,  
21 Sequenom’s President and Chief Executive Officer. “This validation study is an  
22 important next step in our commercialization strategy to bring our noninvasive  
23 Trisomy 21 Down syndrome maternal blood LDT to market.”

24 Thomas J. Garite, M.D., of Obstetrix Medical Group, who will oversee the  
25 study, stated, “The discovery of fetal DNA and RNA in the plasma of pregnant  
26 women has led to promising approaches to noninvasive prenatal testing for the  
27 identification of pregnancies with a chromosomal abnormality such as Down  
28 syndrome. This test could produce results that are more accurate than current early-  
stage serum screening methods, thus reducing the need for invasive tests, such as  
amniocentesis or CVS, which pose a certain level of risk for mother and fetus.”

Dr. Stylli added, “We are committed to becoming a leader in noninvasive  
prenatal diagnostics. As such, Sequenom has taken a three-pronged approach to the  
development and clinical evaluation of the Trisomy 21 technology. First, we  
completed a rigorous R&D study over the last year, the final data from which will be  
announced later today. Second, we initiated this LDT validation study to obtain  
extensive clinical data in support of faster adoption of an LDT by our CLIA-certified  
laboratory, SCMM. Lastly, Sequenom is sponsoring the RNA Noninvasive  
Aneuploidies (“RNA”) study, a landmark, multi-center, prospective study involving  
up to 10,000 samples from first and second trimester pregnancies using the  
SEQuereDx technology, managed and analyzed by an independent third-party.”

32. On February 3, 2009, Sequenom issued a press release entitled “Sequenom  
Announces Findings on Methylation Markers and RNA-SNP Markers as Presented at SMFM –  
Company Provides Additional Details on SEQuereDx Trisomy 21 Technology Performance Data,”  
which stated in part:

1 Sequenom, Inc. today announced new data showing the discovery of DNA  
2 methylation markers for Trisomy 21 (Down syndrome), Trisomy 18 (Edwards  
3 syndrome) and Trisomy 13 (Patau syndrome) and identification of chromosome  
4 RNA-SNP markers for early detection of Trisomies 18 and 13. The data were  
5 presented on Thursday and Friday, January 29 and January 30, 2009, at the 29th  
6 annual meeting of the Society for Maternal-Fetal Medicine (SMFM). In addition,  
7 Sequenom announced more information regarding the performance of its Down  
8 syndrome test at a separate meeting held concurrently in San Diego.

9 “Sequenom is committed to reinforcing its leadership in the noninvasive  
10 prenatal arena with innovative, proprietary technologies for chromosomal disorders,  
11 and monogenic, polygenic diseases using discrete and whole genome approaches,”  
12 said Harry Stylli, Ph.D., President and Chief Executive Officer of Sequenom. “Our  
13 discoveries regarding new DNA methylation and RNA-SNP markers for Trisomies  
14 21, 18, 13 will help expand our future assay offerings. Also, our new, proprietary  
15 DNA-based testing method, which was presented at our analyst meeting,  
16 complements our RNA-based strategy, especially as a reflex for homozygote no  
17 calls. The DNA-based method has the potential to work universally for T21, T18,  
18 T13 and gender determination in a single tube.”

19 In an oral session presented at the SMFM meeting, Mathias Ehrich, M.D.,  
20 Scientific Group Leader of Sequenom, highlighted the discovery of DNA  
21 methylation markers for prenatal aneuploidy testing in a presentation entitled  
22 “Discovery of DNA Methylation Markers for Prenatal Aneuploidy.” The genome-  
23 wide methylation analysis identified more than 3,000 differentially methylated  
24 regions with approximately 90% confirmation; study results showed proof-of-  
25 concept for the sensitive detection of aneuploidies.

26 In a poster session at the SMFM meeting entitled “Identification of RNA-  
27 SNP Markers for Noninvasive Prenatal Diagnosis (NIPD) of T18 and T13,” an exon  
28 array was utilized to compare gene expression profiles and identify SNPs using  
matched placenta and maternal PBMC RNA samples. All SNP candidates were then  
screened using 100 human diversity genomic DNA samples of various ethnicities to  
measure the heterozygote rate (HR) for each SNP. SNPs with an HR of 4 percent or  
greater were retested using placental RNA samples. Four SNPs from one C13 gene  
and three C18 genes were selected for assay development based on positive placental  
RNA results and additional SNPs within these genes will be validated to expand  
population coverage for T13 and T18 screening using the RNA-based method.

The RNA, DNA and methylation marker variations of the SEQuereDx™  
Technology are being developed in parallel and may be validated in the same studies.  
All may ultimately be commercialized and prove complementary in some or all  
patients.

### **Additional Data from Screening Studies Evaluating RNA-based SEQuereDx Trisomy 21 Technology**

During an analyst and investor briefing held concurrently with the SMFM  
meeting, Sequenom presented new data evaluating its prenatal screening technology  
for Down syndrome. The data presented consisted of 459 new samples from  
prospective, blinded studies performed at Sequenom, bringing the total number of  
samples studied to 858. The test correctly identified all 22 T21 positive samples from  
the 459 new samples including eight first-trimester and 14 second-trimester Down  
syndrome samples (i.e. 100% sensitivity or detection rate) with one false positive and  
no false negatives, as confirmed by chorionic villus sampling (CVS) and

1 amniocentesis. The DNA-based method correctly detected the one homozygous  
2 sample that the RNA-based method did not resolve (i.e., that had been deemed a “no-  
3 call”).

4 A summary of the results for the 459 new samples including samples as early  
5 as 8 weeks of pregnancy are as follows:

- 6 • Specificity of 99.7% (98.4% - 100%) and 100% sensitivity (85.1 – 100%) at  
7 a 95 % confidence interval;
- 8 • The Positive Predictive Value is 95.6% (79.0% -99.8%) and the Negative  
9 Predictive Value of 100.0% (98.9% - 100%) at a 95% confidence interval;
- 10 • The SEQuREdx RNA test had a total of 85 unresolved results (“no-calls”) due  
11 to homozygotes (80) and unacceptably low RNA levels (5) for a total of  
12 18.5%. The DNA-based method analyzed 68 of the homozygote “no-calls”  
13 and all were successfully resolved;
- 14 • The distribution of the 459 samples actually collected as compared to the  
15 expected rate in the U.S. population was Caucasian (282 vs. 307), Asian (101  
16 vs. 20), African American (12 vs. 62) Hispanic (62 vs. 68) and Native  
17 American (2 vs. 3).

18 “We are pleased with the progress of our research efforts and look forward to  
19 transferring the technology to our CLIA facility soon for commercial launch in  
20 June,” said Dr. Betty Dragon, Senior Vice President Research & Development. “We  
21 are confident that our no call rate for homozygote samples will improve as the patient  
22 population increases and the ethnic distribution normalizes. We expect that in the  
23 final test, ethnic coverage will be better than 95% of the U.S. population.  
24 Identification of additional SNPs by ongoing sequencing of the relevant genes of  
25 homozygote patients, coupled with modest improvements in marker recovery, will  
26 further expand the ethnic coverage of the RNA-based test.

27 “Furthermore, when compared to amniocentesis or CVS, the new DNA-based  
28 method correctly identified all 68 homozygotes tested including a no-call T21 sample  
and a no call T18 sample. The DNA-based test shows great promise as a reflex to the  
RNA method or potentially as a front-line test in its own right,” added Dr. Dragon.

Based on the results from the 858 total study samples, the Sequenom  
SEQuREdx RNA-based technology demonstrated:

- Specificity of 99.9% (99.2% - 100.0%) and 100% sensitivity (87.9% -  
100.0%) at a 95% confidence interval;
- The Positive Predictive Value is 96.6% (82.8% -99.8%) and the Negative  
Predictive Value of 100.0% (99.5% - 100%) at a 95% confidence interval;
- The SEQuREdx RNA test had a total of 106 unresolved results (“no calls”)  
due to homozygotes (94) and unacceptable RNA levels (12) or a total of  
12.4%. The DNA-based method, when applied, resolved all no calls;
- SEQuREdx is considerably more accurate than commonly employed  
standard-of-care screening tests, which perform at a 70%-90% detection rate  
(i.e., sensitivity) with a 90%-95% specificity in practice. SEQuREdx even

1 compares favorably to current invasive procedures, such as amniocentesis  
2 (which has sensitivity and specificity of approximately 99.5%).

3 33. On February 11, 2009, Sequenom issued its fourth quarter and year end 2008  
4 financial results, in a release which stated in part:

5 Sequenom, Inc. today reported financial results for the three and 12 months ended  
6 December 31, 2008.

7 “This past year was pivotal for Sequenom as we continued to advance our  
8 genetic analysis and molecular diagnostics businesses,” stated Harry Stylli, Ph.D.,  
9 President and Chief Executive Officer of Sequenom. “We accomplished many key  
10 milestones over the last 12 months and are well-positioned for the launch of our  
11 SEQuereDx™ Down syndrome technology in June. The data reported from our R&D  
12 study containing 858-patient samples clearly shows that our SEQuereDx screening  
13 technology is considerably more accurate than the current standard-of-care screening  
14 technology, and even compares favorably against current invasive procedures. We  
15 intend to review in extensive detail the specifics of our promising study results and  
16 commercialization milestones by dedicating substantial time to these during our  
17 quarterly investment-community conference call later today.”

18 \* \* \*

#### 19 **Early 2009 Highlights**

- 20 • *Announced Additional Positive Results from RNA Down Syndrome Screening  
21 Study and Unveiled Breakthrough DNA Approach to Prenatal Diagnostics:*  
22 Earlier this year, Sequenom announced positive data regarding the  
23 performance of its Down syndrome test, including data from 459 new, high-  
24 prevalence patient samples, bringing the total number of patient samples  
25 studied to 858. Based on the results from total study samples, including  
26 samples obtained as early as eight weeks of pregnancy, Sequenom’s  
27 SEQuereDx RNA-based technology demonstrated a 96.6% positive predictive  
28 value (PPV) and a 100% negative predictive value (NPV). Sequenom also  
unveiled a breakthrough DNA-based SEQuereDx technology demonstrating,  
in early studies, universal ethnic coverage, high sensitivity and specificity,  
and the ability to detect Trisomy 21 (Down syndrome), Trisomy 18 (Edwards  
syndrome) and Trisomy 13 (Patau syndrome) in a single test.

\* \* \*

#### 29 **Fourth Quarter 2008 Highlights**

- 30 • *New Data Indicates Next-generation Noninvasive Technology Accurately  
31 Quantifies Maternal Plasma DNA Sequences for Down syndrome:* In  
32 December Sequenom announced new data from a collaborative project with  
33 The Chinese University of Hong Kong, published in the Early Edition of the  
34 Proceedings of the National Academy of Sciences, that demonstrate  
35 Sequenom’s innovative, next-generation, noninvasive prenatal diagnostic  
36 technology accurately quantified maternal plasma DNA sequences for Down  
37 syndrome, based on samples taken from women in the first and second  
38 trimesters of pregnancy. These data are the first to suggest that this future  
approach, based on massively parallel genomic DNA sequencing, can be  
effective in women who had not previously undergone invasive procedures.

1 34. On March 12, 2009, Sequenom filed its annual report on Form 10-K for the year  
2 ended December 31, 2008, which was signed by defendants Stylli and Hawran and represented that:

3 In the near term, we are targeting a \$2 billion prenatal screening opportunity  
4 with our prenatal Down syndrome and Rhesus D genotyping products. Cystic fibrosis  
5 carrier screening, which is often ordered when Down syndrome screening is  
performed is estimated to be a market worth an additional \$250 to \$750 million  
based on the different product offerings available in the United States today.

6 \* \* \*

7 Based on the results from the 858 total study samples, our SEQuReDx RNA-  
8 based technology demonstrated:

- 9 • Specificity of 99.9% (99.2%-100.0%) and 100% sensitivity (87.9%-  
100.0%) at a 95% confidence interval;
- 10 • The Positive Predictive Value is 96.6% (82.8%-99.8%) and the  
11 Negative Predictive Value of 100.0% (99.5%-100%) at a 95%  
confidence interval;
- 12 • The SEQuReDx RNA test had a total of 106 unresolved results  
13 (“inconclusives”) due to homozygotes (94) and unacceptable RNA  
14 levels (12) or a total of 12.4%. (The DNA-based method, when  
applied, resolved the no calls of those samples which could be  
tested);
- 15 • SEQuReDx is more accurate than commonly employed standard-of-  
16 care screening tests, which perform at a 70%-90% detection rate (i.e.,  
sensitivity) with a 90%-95% specificity in practice. SEQuReDx even  
17 compares favorably to current invasive procedures, such as  
amniocentesis (which has sensitivity and specificity of approximately  
18 99.5%).

19 “Specificity” is the probability that the test will be negative if the patient does  
20 not have the disease or condition. “Sensitivity” is the probability that the test will be  
21 positive if the patient has the disease or condition. “Positive Predictive Value” is the  
22 probability that a patient has the disease or condition when his/her test is positive.  
“Negative Predictive Value” is the probability that a patient does not have the disease  
or condition when his/her test is negative. The ranges in parentheses are 95%  
confidence intervals which represent the statistical uncertainty associated with the  
results based on the sample data.

23 35. The Form 10-K also included certifications by Stylli and Hawran, which certifications  
24 stated in part:

25 1. I have reviewed this annual report on Form 10-K for the year ended  
26 December 31, 2008 of Sequenom, Inc.;

27 2. Based on my knowledge, this annual report does not contain any untrue  
28 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 annual report;

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

\* \* \*

4. The registrant's other certifying officer(s) and I am 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 annual report is being prepared;

36. On April 29, 2009, after the market closed, the Company issued a press release entitled "Sequenom Announces Delay in Launch of SEQureDx Trisomy 21 Test." The press release stated in part:

SEQUENOM, Inc. announced today that the expected launch of its SEQureDx™ Down syndrome test is delayed, due to the discovery by company officials of employee mishandling of R&D test data and results. Accordingly the company is no longer relying on the previously announced R&D test data and results. SEQUENOM has not changed its plans to develop in parallel its RNA- and DNA-based methods for the Down syndrome test and will endeavor to have a validated test in the fourth quarter of 2009. Under the circumstances, and as supported by key clinical opinion leaders, the company now intends to launch the Down syndrome test upon publication in a peer-reviewed journal of the results from the on-going large, independent clinical studies, which are designed to be practice-changing for Down syndrome testing.

The company's board of directors has formed a special committee of independent directors to oversee an independent investigation of the employees' activity related to the test data and results. The committee has engaged independent counsel to assist the committee in the conduct of the investigation.

\* \* \*

Today's announcement regarding the company's SEQureDx Down syndrome R&D test data and results supersedes all previous announcements about such data and test, including its press releases dated June 4, 2008, September 23, 2008, December 1, 2008, January 28, 2009 and February 3, 2009.

37. On this news, Sequenom's stock collapsed more than \$11 per share to as low as \$3.23 per share, a one-day decline of over 75%, on volume of more than 85 million shares.

38. The true facts, which were known by the defendants but concealed from the investing public during the Class Period, were as follows:

1 (a) Company employees mishandled test data and results concerning Sequenom's  
2 Down syndrome test; and

3 (b) The Company failed to maintain internal controls sufficient to prevent the  
4 mishandling of test data and results.

5 39. As a result of defendants' false statements, Sequenom's stock price traded at inflated  
6 levels during the Class Period. This drop removed inflation from Sequenom's stock price, causing  
7 real economic loss to investors who had purchased the stock during the Class Period.

8 **LOSS CAUSATION/ECONOMIC LOSS**

9 40. By misrepresenting its testing processes and results, the defendants presented a  
10 misleading picture of Sequenom's business and prospects. Thus, instead of truthfully disclosing  
11 during the Class Period that Sequenom's testing did not have adequate controls over employees  
12 involved in testing data, Sequenom falsely reported positive test results.

13 41. These claims of favorable data caused and maintained the artificial inflation in  
14 Sequenom's stock price throughout the Class Period and until the truth was revealed to the market.

15 42. On April 29, 2009, defendants were forced to publicly disclose that Sequenom  
16 employees had "mishandled" data with respect to the all-important Down syndrome testing  
17 technology, causing its stock to collapse from \$14.91 per share to as low as \$3.23 per share in one  
18 day.

19 43. As a direct result of defendants' admissions and the public revelations regarding the  
20 truth about Sequenom's overstatement of income and its actual business prospects going forward,  
21 Sequenom's stock price fell more than 73%, falling from \$14.91 per share on April 29, 2009 to as  
22 low as \$3.23 per share on April 30, 2009 – a one-day drop of more than \$11 per share. This drop  
23 removed the inflation from Sequenom's stock price, causing real economic loss to investors who had  
24 purchased the stock during the Class Period.

25 **COUNT I**

26 **For Violation of §10(b) of the 1934 Act and Rule 10b-5**  
27 **Against All Defendants**

28 44. Plaintiff incorporates ¶¶1-43 by reference.



1 **CLASS ACTION ALLEGATIONS**

2 50. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules  
3 of Civil Procedure on behalf of all persons who purchased or otherwise acquired Sequenom common  
4 stock during the Class Period (the "Class"). Excluded from the Class are defendants.

5 51. The members of the Class are so numerous that joinder of all members is  
6 impracticable. The disposition of their claims in a class action will provide substantial benefits to  
7 the parties and the Court. Sequenom has more than 60 million shares of stock outstanding, owned  
8 by hundreds if not thousands of persons.

9 52. There is a well-defined community of interest in the questions of law and fact  
10 involved in this case. Questions of law and fact common to the members of the Class which  
11 predominate over questions which may affect individual Class members include:

- 12 (a) whether the 1934 Act was violated by defendants;
- 13 (b) whether defendants omitted and/or misrepresented material facts;
- 14 (c) whether defendants' statements omitted material facts necessary to make the  
15 statements made, in light of the circumstances under which they were made, not misleading;
- 16 (d) whether defendants knew or deliberately disregarded that their statements  
17 were false and misleading;
- 18 (e) whether the price of Sequenom common stock was artificially inflated; and
- 19 (f) the extent of damage sustained by Class members and the appropriate measure  
20 of damages.

21 53. Plaintiff's claims are typical of those of the Class because plaintiff and the Class  
22 sustained damages from defendants' wrongful conduct.

23 54. Plaintiff will adequately protect the interests of the Class and has retained counsel  
24 who are experienced in class action securities litigation. Plaintiff has no interests which conflict  
25 with those of the Class.

26 55. A class action is superior to other available methods for the fair and efficient  
27 adjudication of this controversy.

28

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

**PRAYER FOR RELIEF**

WHEREFORE, plaintiff prays for judgment as follows:

- A. Declaring this action to be a proper class action pursuant to Fed. R. Civ. P. 23;
- B. Awarding plaintiff and the members of the Class damages, including interest;
- C. Awarding plaintiff reasonable costs and attorneys' fees; and
- D. Awarding such equitable/injunctive or other relief as the Court may deem just and

proper.

**JURY DEMAND**

Plaintiff demands a trial by jury.

DATED: May 1, 2009