FLUIDIGM CORP Form 10-K March 26, 2012 **Table of Contents** 

## **UNITED STATES**

## SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **FORM 10-K**

(Mark One)

#### ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT Х **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** to

For the transition period from

Commission file number: 001-34180

# FLUIDIGM CORPORATION

(Exact name of registrant as specified in its charter)

## Edgar Filing: FLUIDIGM CORP - Form 10-K

Delaware

(State or other jurisdiction of

incorporation or organization)

7000 Shoreline Court, Suite 100

South San Francisco, California 94080

(Address of principal executive offices) (Zip Code)

(650) 266-6000

Registrant s telephone number, including area code

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

Title of each class Name of each exchange on which registered Common Stock, \$0.001 Par Value per Share The NASDAQ Global Market 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 of 1933, as amended. Yes " No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended. Yes " No x

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 x No

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

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

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 " Non-accelerated filer x (Do not check if a smaller reporting company) Smaller reporting company " Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes "No x

As of June 30, 2011, the last business day of the registrant s most recently completed second fiscal quarter, the aggregate market value of voting and non-voting common equity held by non-affiliates of the registrant was approximately \$181,673,552 (based on a closing sale price of \$16.77

#### 77-0513190 (I.R.S. Employer

**Identification Number**)

Accelerated filer

## Edgar Filing: FLUIDIGM CORP - Form 10-K

per share as reported for the NASDAQ Global Market on June 30, 2011). For purposes of this calculation, shares of common stock beneficially owned by the registrant s current officers and directors as of June 30, 2011 and shares of common stock held by persons who currently hold more than 10% of the outstanding common stock of the registrant (based solely upon Schedule 13G filings made with the SEC in February 2012) have been excluded from this calculation because such persons may be deemed to be affiliates. This determination of executive officer or affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares of the registrant s common stock, \$0.001 par value per share, outstanding as of February 29, 2012 was 20,421,444.

#### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s definitive Proxy Statement relating to its 2012 Annual Meeting of Stockholders are incorporated by reference into Part III of this Form 10-K where indicated.

## Fluidigm Corporation

Fiscal Year 2011

## Form 10-K

**Annual Report** 

## TABLE OF CONTENTS

		Page
PART I		
ITEM 1.	BUSINESS	1
ITEM 1A.	<u>RISK FACTORS</u>	25
ITEM 1B.	UNRESOLVED STAFF COMMENTS	45
ITEM 2.	PROPERTIES	45
ITEM 3.	LEGAL PROCEEDINGS	45
ITEM 4.	MINE SAFETY DISCLOSURE	45
PART II		
ITEM 5.	MARKET FOR REGISTRANT S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUE	R
	PURCHASES OF EQUITY SECURITIES	46
ITEM 6.	<u>SELECTED FINANCIAL DATA</u>	48
ITEM 7.	MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF	
	<u>OPERATIONS</u>	49
ITEM 7A.	QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	68
ITEM 8.	FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA	69
ITEM 9.	CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL	
	DISCLOSURE	105
ITEM 9A.	CONTROLS AND PROCEDURES	105
ITEM 9B.	OTHER INFORMATION	105
PART III		
ITEM 10.	DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE	106
ITEM 11.	EXECUTIVE COMPENSATION	106
ITEM 12.	SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED	
	STOCKHOLDER MATTERS	106
ITEM 13.	CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE	106
ITEM 14.	PRINCIPAL ACCOUNTING FEES AND SERVICES	106
PART IV		
ITEM 15.	EXHIBITS, FINANCIAL STATEMENT SCHEDULES	107

i

#### Special Note Regarding Forward-looking Statements and Industry Data

This Form 10-K contains forward-looking statements that are based on our management s beliefs and assumptions and on information currently available to our management. The forward-looking statements are contained principally in the sections entitled Risk factors, Management s discussion and analysis of financial condition and results of operations, and Business. Forward-looking statements include information concerning our possible or assumed future results of operations, business strategies, financing plans, competitive position, industry environment, potential growth opportunities and the effects of competition. Forward-looking statements include statements that are not historical facts and can be identified by terms such as anticipates, believes, could, seeks, estimates, expects, intends, may, plans, potential, privail, would or similar expressions and the negatives of those terms.

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. We discuss these risks in greater detail in the section entitled Risk factors and elsewhere in this Form 10-K. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

Forward-looking statements represent our management s beliefs and assumptions only as of the date of this Form 10-K. Except as required by law, we assume no obligation to update these forward-looking statements, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future. You should read this Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect.

## **Corporate information**

We were incorporated in California in May 1999 as Mycometrix Corporation, changed our name to Fluidigm Corporation in April 2001 and reincorporated in Delaware in July 2007. Our principal executive offices are located at 7000 Shoreline Court, Suite 100, South San Francisco, California 94080. Our telephone number is (650) 266-6000. Our website address is www.fluidigm.com. Information contained on our website is not incorporated by reference into this Form 10-K and should not be considered to be part of this Form 10-K.

Fluidigm, the Fluidigm logo, BioMark, Dynamic Array, Digital Array, Access Array, EP1, FC1, MSL, NanoFlex, SNPtype a trademarks or registered trademarks of Fluidigm Corporation. Other service marks, trademarks and trade names referred to in this Form 10-K are the property of their respective owners.

predicts,

#### PART I

#### ITEM 1. BUSINESS Overview

We develop, manufacture and market microfluidic systems for growth markets, such as single-cell genomics, applied genotyping and sample preparation for targeted resequencing, in the life science and agricultural biotechnology, or Ag-Bio, industries. Our proprietary microfluidic systems consist of instruments and consumables, including chips, assays and other reagents. These systems are designed to significantly simplify experimental workflow, increase throughput and reduce costs, while providing the excellent data quality demanded by customers. In addition, our proprietary technology enables genetic analysis that in many instances was previously impractical. We actively market three microfluidic systems, including eight different commercial chips for nucleic acid research and three families of assays, to leading academic institutions, diagnostic laboratories, and pharmaceutical, biotechnology and Ag-Bio companies. We have sold over 500 systems to customers in over 25 countries worldwide.

To achieve and exploit advances in life science research, Ag-Bio and molecular diagnostics, laboratories need robust systems that deliver high throughput and simpler workflows at decreased costs. Our microfluidic systems are designed to overcome many of the limitations of conventional laboratory systems by integrating a vast number of fluidic components on a single microfabricated chip. Our technology enables our customers to perform and measure thousands of sophisticated biochemical reactions on samples smaller than the content of a single cell, while utilizing minute volumes of reagents and samples. Similarly, for next generation DNA sequencing, our systems enable rapid preparation of multiple samples in parallel at low cost.

We have successfully commercialized our BioMark, BioMark HD and EP1 systems for genetic analysis and our Access Array system for next generation DNA sequencing sample preparation. Researchers and clinicians have successfully employed our products to help achieve breakthroughs in a variety of fields, including single-cell genomics, genetic variation, cellular function and applied genetics. These include using our microfluidic systems to help detect life-threatening mutations in patients cancer cells, discover cancer associated biomarkers, analyze the genetic composition of individual stem cells, and assess the quality of agricultural products, such as seeds or livestock. We believe our Access Array system resolves a critical workflow bottleneck that exists in all commercial next generation DNA sequencing platforms and provides fast, simple, low-cost preparation of samples for targeted resequencing. We expect that the versatility of our microfluidic technology will enable us to develop additional applications across a wide variety of markets.

We have grown our total revenue from \$25.4 million in 2009 to \$42.9 million in 2011. Our product margin has increased from 51% in 2009 to 67% in 2011. We have incurred significant net losses since our inception, including net losses of \$32.4 million in 2011.

#### **Our Target Markets**

The current markets for our products include life science research and Ag-Bio. In addition, we are developing products for use in molecular diagnostics and other markets.

#### Life Science Research

Our primary area of focus within life science research is genetic analysis, the study of genes and their functions. The sum total of the hereditary material of an organism is known as its genome, which is commonly organized into functional units known as genes. Analysis of variations in genomes, genes and gene activity in and between organisms can provide tremendous insight into their health and functioning. There are several forms of genetic analysis in use today, including gene expression analysis, genotyping and DNA sequencing.

Gene expression and genotyping are studied through a combination of various technology platforms that characterize gene function and genetic variation. These platforms often rely on polymerase chain reaction, or PCR, amplification to generate exponential copies of a DNA sample to provide sufficient signal to facilitate detection. Real-time quantitative PCR, or real-time qPCR, is a more advanced form of PCR that makes it possible to identify the number of copies of DNA present in a sample.

The scale of genetic research varies widely. At one end, researchers sometimes examine a limited number of genetic variations in a relatively small population. At the other end, researchers may perform genome-wide association studies where hundreds of thousands of possible genetic variations are examined across thousands or tens of thousands of samples. Researchers are rarely able to discover scientifically relevant information by examining just a few genetic variations because of the inherent complexity of biological systems. In contrast, the result of many genome-wide association studies is simply the identification of a more limited set of genetic variations that need to be examined in a larger population. As a result, some of the most productive life science research is done at a mid-multiplex scale, where tens or hundreds of genetic variations are examined in hundreds of samples.

We target the following specific areas of life science research, and our products are used for mid-multiplex research or applications of a similar scale:

*Gene Expression Analysis*. Gene expression analysis is a form of genetic analysis that focuses on measuring gene expression. The genome is typically made up of DNA, except in some viruses which utilize RNA. Typically, the process of gene expression involves the generation of RNA copies of specific regions of the genome by a process known as transcription. Such RNA copies are known as messenger RNAs. Messenger RNAs may then be translated by the cell into a protein which may affect the activity of the cell or the larger organism. One prevalent form of gene expression analysis measures the levels of messenger RNA in an individual cell to determine how the activity of particular genes or sets of genes affect the cell or the organism.

*Genotyping*. Genotyping involves the analysis of variations across individual genomes. A common application of genotyping focuses on analyzing variations of single nucleotides, known as a single nucleotide polymorphism, or SNP. In SNP genotyping studies, statistical analyses are performed to determine whether a SNP or group of SNPs are associated with a particular characteristic, such as propensity for a disease. Haplotyping is an application of genotyping in which SNPs located at different loci on the same chromosome are studied simultaneously.

*Single-Cell Genomics*. Single-cell genomics is a rapidly emerging area of genetic research that requires specialized tools and techniques. Genetic research typically involves the analysis of samples containing thousands of cells and many different cell types. When such samples are studied using traditional gene expression analysis, the results obtained reflect a rough average of the activity of all of the cells in the sample. Recently, researchers have demonstrated that this approach often masks critical differences in gene expression levels between different cell types and even between individual cells of the same type. In addition, in the fields of in-vitro fertilization and stem cell research, research has often been constrained because the number of cells available for analysis is inherently limited. The scope of this research has often been a few genes. Furthermore, large numbers of samples are required to determine the heterogeneous signatures of sub-populations of cells and large research studies like these can be prohibitively expensive or impractical when performed on conventional platforms. Single-cell genomic researchers need to conduct a high number of tests on a large volume of cells, which in combination translates into thousands of experiments that must be accurate, fast, simple and low cost.

Sample Preparation for Next Generation DNA Sequencing. Through a process known as sequencing, researchers are able to determine the particular order of nucleotide bases that comprise all or a portion of a particular genome. In the last few years, researchers have begun to use next generation DNA sequencers to

rapidly and cost-effectively sequence portions of the genomes of many individuals and identify genetic variations that correlate with particular characteristics. Next generation DNA sequencing technologies have dramatically reduced the cost and processing time for genetic sequencing, but to be utilized effectively, require large numbers of unique samples. In addition, next generation DNA sequencing requires new sample preparation methodologies, including adding identification tags to each segment of each individual sample that is to be sequenced. These sample preparation and tagging processes, known as target enrichment, are complex and require precise measurement and manipulation of minute quantities of DNA and reagents.

*Digital PCR.* Digital PCR allows researchers to detect nucleic acid sequences that are present in sample concentrations that are too small to be accurately measured by conventional methods. Digital PCR typically relies on standard PCR techniques, but increases their sensitivity by dividing a sample into hundreds or thousands of smaller samples and then performing a PCR assay on each such sample. The ability to count the presence or absence of amplification in this assay format allows for absolute quantitative measurement capabilities. As a result, digital PCR can perform more precise detection of rare mutations, or copy number measurements, as compared to real-time qPCR.

#### Agricultural Biotechnology

Genetic analysis techniques, such as SNP genotyping, have become increasingly useful in Ag-Bio applications, including wildlife population studies, agricultural quality control and commercial genetic engineering and identification. These applications typically require the analysis of hundreds or thousands of SNPs to achieve representative samples and attain useful information. Due to these demands, commercially viable genetic analysis tools in Ag-Bio must be inexpensive, easy to use and able to provide extremely high throughput. Below a certain cost per data point, we believe Ag-Bio customers would choose to analyze the genome of each animal or sample.

#### **Molecular Diagnostics**

Recent advances in genetic analysis technology are increasingly being used for clinical applications. Techniques such as SNP genotyping, gene expression analysis and other genetic correlation studies are used to identify disease susceptibility and to diagnose, classify and monitor disease progression. Molecular diagnostic tests based on measuring these genetic markers have the potential to be much more accurate and robust than conventional diagnostics. Within molecular diagnostics, an area of significant clinical interest is non-invasive prenatal diagnostics, or NIPD, for fetal aneuploidies. The traditional diagnostic tests are invasive and carry risks to the fetus. More recently, other diagnostics tests based on next generation DNA sequencing have become available and are not invasive. We are collaborating with Novartis Vaccines & Diagnostics, Inc., or Novartis V&D, to develop products to target this NIPD market for fetal aneuploidies.

#### The Limitations of Existing Laboratory Systems

Academic, clinical and industrial researchers are increasingly performing genetic analysis on large sample sizes and assay sets. These experiments are typically performed using systems consisting of 384 well or larger microplates, pipetting stations, robotic plate movers and other elements of laboratory equipment. However, these conventional systems require an extremely complex workflow involving thousands of pipetting steps, hundreds of microplates and, despite the use of robotics, extensive human intervention. Such complexity limits the throughput of laboratories and increases the possibility of errors and variability between experiments. In addition, these systems typically are unable to perform experiments with low fluid volumes, leading to excessive consumption of reagents and inconsistent results.

In response to the limitations of conventional systems, numerous other methods of genetic analysis, including microarrays, pre-formatted arrays, bead arrays, microdroplets and mass spectrometer analysis have been developed. However, each of these high-throughput methods has one or more limitations that reduce its

utility, particularly for mid-multiplex experimentation. Microarrays, pre-formatted arrays and bead arrays all lack flexibility because researchers must specify the assays they wish to perform at the time the products are ordered. This in turn limits researchers ability to refine their assay panel during the course of a study. In addition, if researchers wish to use assay panels other than a manufacturer s standard panels, they must wait for a customized product to be produced.

The quality of the data produced by microarrays, pre-formatted arrays and mass spectrometer analysis is insufficient for certain research activities. For genotyping studies, data quality is typically measured by call rate, which is the frequency of a reading with respect to a particular SNP. Both pre-formatted arrays and mass spectrometer analysis generally have call rates lower than real-time qPCR performed in microplates. For gene expression studies, it is often important to measure expression levels over a broad dynamic range to capture all or most of the variation found among subjects. Microarrays, pre-formatted arrays, bead arrays or mass spectrometer analysis cannot measure gene expression levels over as broad a dynamic range as real-time qPCR performed in microplates. In addition, most of these techniques require large sample volumes making single-cell expression analysis impossible or inaccurate.

The workflow for bead arrays and mass spectrometer analysis is complex, time consuming and costly. For example, standard protocols often require multiple complex operations to be performed over several days by skilled technicians. Also, certain pre-formatted arrays require significant manual intervention, which significantly increases costs and potential for error. These methods can also be very costly for mid-multiplex experimentation. For example, a single microarray or bead array is capable of analyzing thousands of genes from a single sample. These devices have been successfully used for surveying the genome to discover basic patterns of genetic variation. These surveys are commonly performed on tens or hundreds of samples and are intended to identify a subset of genes for further investigation. However, for validation studies, which typically require the analysis of thousands or tens of thousands of samples, the high per sample cost of microarrays and bead arrays often make them uneconomical. Similarly, the high initial setup costs for mass spectrometry analysis generally make it economically feasible only for very large-scale studies.

While the cost and processing time for genetic sequencing has plummeted with next generation DNA sequencing technologies, improvements in sample preparation has lagged to the extent that sample preparation now represents the major bottleneck from both a cost and time perspective in the sequencing process. Microdroplet technologies have been proposed as a means to accelerate the sample preparation and tagging process for next generation DNA sequencing. However, this technique can process only one sample at a time, is expensive and cannot be validated prior to sequencing.

The limitations of existing technologies become even more acute when clinicians attempt to translate scientific research into commercial molecular diagnostics. Given the nature of their operations, commercial clinical laboratories need systems that can test large numbers of patient samples at low cost and with minimal labor requirements. Moreover, many of the most promising research studies rely on measuring each sample across tens or even hundreds of genetic markers to diagnose or classify a disease. We believe that using standard microplate technology to make multiple measurements on a large number of samples is often too complex and expensive for most clinical laboratories. Similarly, many of the limitations of microarrays, pre-formatted arrays, bead arrays and microdroplets also impact their ability to provide a broadly acceptable molecular diagnostic solution. As a result, the molecular diagnostic tests adopted by clinical laboratories have generally been relatively simple or have required specialized machines to perform. Diagnostic approaches that require measuring large numbers of genetic markers are generally not available or are available only from a diagnostic laboratory that specializes in the particular test.

Researchers, clinicians and commercial users need more robust systems that deliver increased throughput and simpler workflows with decreased costs.

#### **The Fluidigm Solution**

Our proprietary microfluidic systems are designed to significantly simplify experimental workflow, increase throughput, reduce costs, provide excellent data quality and, in many instances, enable genetic analysis that was previously impractical. Our microfluidic systems empower researchers and commercial customers to rapidly perform significantly more experiments or prepare significantly more samples all at one time and in nanoliter volumes with a combination of speed and accuracy that we believe cannot be achieved with other systems. Our systems deliver these advantages through the integration of sophisticated nanoliter fluid handling in an easy-to-use format that is compatible with most existing laboratory workflows and chemistries. Our systems are used in existing and emerging life science research and Ag-Bio markets, and we believe there are significant growth opportunities in additional markets. A significant portion of our research and development efforts are currently focused on enabling more research in the field of single-cell genomics or driving potential applications of our technology in molecular diagnostics. We expect such development focus to continue.

We believe that our microfluidic systems have a number of compelling advantages over microplate systems and other mid-multiplex platforms including:

*Data Quality*. Our microfluidic systems provide exceptionally high quality data. In genotyping, our systems achieve greater than 99% call rate and call accuracy. For gene expression, our systems achieve six orders of magnitude of dynamic range with inter- and intra-chip reproducibility at correlation coefficients greater than 0.99, even when analyzing just a single cell.

*Improved Throughput*. Our BioMark HD system can generate over 46,000 genotyping data points per day and high throughput configurations of our system can generate over 110,000 data points per day, with a time to first result measured in hours. Some competing systems may offer comparable data points per day, but may take longer for first results. Other systems offer comparable time to first result, but produce fewer data points per day, and often with lower data quality. Our improved throughput reduces the time and cost associated with complex experiments and expands the number and range of experiments that may be conducted.

*Ease of Use.* Loading our 96.96 Dynamic Array chip requires 192 pipetting steps as compared to 18,432 steps required to load the number of 384 well microplates required for the same experiment. Difficulties encountered with some competing systems include manual sample loading and chip alignment that often results in lower throughput. We believe our microfluidic systems efficient workflow reduces time, cost and potential for error.

*Flexibility*. Our chips are built on input frames that are compatible with most commonly used laboratory systems, including existing robotic pipetting systems, bar code readers, plate handling systems and other equipment. Our chips are also designed to work with our own chemistries or with standard chemistries. In addition, our chips give researchers the flexibility to develop and load their own assays, unlike some competing products that can be used only to analyze specific genes or that are supplied pre-configured with fixed content.

*Nanoliter Precision.* Our microfluidic systems allow users to dispense samples and reagents in microliter volumes which are automatically partitioned, combined or mixed in nanoliter and sub-nanoliter volumes. In addition to cost and workflow benefits, this capability makes it practical for users to conduct certain high sensitivity, low volume techniques, such as digital PCR and single-cell analysis.

*Cost-Effectiveness*. We believe our high throughput systems offer a compelling cost benefit for high volume users. Our systems consume reagents in nanoliter volumes and have the ability to conduct thousands of parallel experiments on one chip. When used in conjunction with our SNPtype and DELTAgene reagents, up-front experimental costs are also reduced.

We provide complete microfluidic systems consisting of instruments and consumables, including chips, assays and other reagents. Our systems are easily incorporated into our customers laboratory environments and

analysis workflow. For example, our chips are the same size and shape as standard 384 well microplates and other chip consumables, which facilitate the loading and handling of our chips by standard laboratory equipment. Each of our chips includes an elastomeric, or rubber-like, core that contains an extensive network of microfluidic components that deliver samples and reagents to thousands of nanoliter volume chambers where individual assays are performed. Our primary product offerings are summarized in the table below:

Product Instruments	Product Description	Applications				
instruments						
BioMark HD System	Real-time PCR instrument, bundled analysis software and chip loading platforms	SNP Genotyping, Digital PCR and Gene Expression, including Single-Cell Analysis				
EP1 System	End-point PCR instrument, bundled analysis software and chip loading platforms	SNP Genotyping and Digital PCR				
Access Array System	Sample preparation system for targeted resequencing that facilitates parallel amplification of 48 unique samples	Targeted Resequencing with Next Generation DNA Sequencing				
Consumables						
Dynamic Array Chips	Microfluidic chip based on matrix architecture, allowing users to generate up to 9,216 real-time qPCR reactions simultaneously	Real-time qPCR, SNP Genotyping and Gene Expression, including Single-Cell Analysis				
Digital Array Chips	Microfluidic chip based on partitioning architecture, allowing users to divide each of up to 48 separate samples into 770 smaller samples	Digital PCR, Gene Expression, Copy Number Variation and Mutation Detection				
Access Array Chips	Microfluidic chip that facilitates parallel amplification, barcoding and tagging of 48 unique samples	Targeted Resequencing with Next Generation DNA Sequencing				
DELTAgene and SNPtype Reagent Kits	Custom designed assays for specific nucleic acid regions of interest	Targeted Resequencing with Next Generation DNA Sequencing, SNP Genotyping and Gene Expression, including Single-Cell Analysis				
Access Array Target-Specific Primers	Allows for fast, simple and inexpensive preparation of up to 480 amplicons per sample at a time	Targeted Resequencing with Next Generation DNA Sequencing				
Current Commercial Applications						

We believe our microfluidic systems offer distinct advantages for mid-multiplex analysis in each of our target markets:

#### Life Science Research

*Gene Expression and Genotyping*. Our systems provide researchers a flexible and easy to use tool for generating high quality data. Competing technologies, such as pre-formatted arrays, bead arrays and microarrays,

are limited and inflexible because they require nucleic acid sequences on the device to be pre-specified when the chip or other consumable is manufactured. In contrast, our microfluidic systems allow researchers to utilize and easily tailor their assays to meet their experimental needs, which can shorten the analytical cycle for a given study to hours instead of weeks. We believe our systems also offer meaningful cost savings because they operate on nanoliter volumes of reagents and samples, which are between 0.5% and 1.0% of the amount required by conventional microplate systems.

For example, a consortium consisting of a major research university, a fertility clinic and a regenerative medicine and research group has utilized our systems to conduct research in in-vitro fertilization. By performing individual expression profile analyses, this group has discovered a set of factors implicated in the survival and maturation of human eggs, leading to improved success in fertility clinics.

*Single-Cell Genomics*. The integrated workflow and precision of our systems enable researchers to perform gene expression analysis on single cells on a scale that is impractical with conventional systems. Information gathered on cell activities has traditionally been obtained from populations of cells due to technological limitations on the ability to examine each individual cell. Our systems are able to precisely divide the limited amount of sample material extractable from a single cell into a multitude of divisions, and then accurately assay each such minute division. The high throughput of our systems allows researchers to analyze thousands of cells in this manner. For example, our BioMark HD system can deliver over 46,000 single cell data points in one day and high throughput configurations of our system can generate over 110,000 data points per day. Providing the combination of high throughput and data quality necessary for single-cell analysis presents significant challenges that we believe most conventional systems are unable to address in a practical manner. Our technology excels in offering a unique combination of these attributes for single-cell genomic researchers.

For example, our BioMark system has been used to help identify specific signatures of cancer stem cells at the single cell level. Researchers believe that certain cancer stem cells are precursors to certain tumors and are often manifested well in advance of other tumor markers. By detecting and identifying such cells, researchers believe they can diagnose and treat cancer at a much earlier stage than with conventional methods. In addition, our BioMark system has been used to identify signatures of induced pluripotent stem, or iPS, cells. These iPS cells may have multiple applications in life science research and therapeutics. Similarly, our BioMark system has also been used to identify signatures of immune system cells, both pre- and post- exposure to antigens, to gain insight into improved vaccines and disease treatments. As of December 31, 2011, over 80 of our BioMark systems were being used to perform single-cell analysis.

Sample Preparation for Targeted Resequencing with Next Generation DNA Sequencing. To efficiently use next generation sequencers to perform validation or other studies, researchers need to be able to prepare and tag samples from tens or hundreds of individuals prior to the samples being processed by the sequencers. Using conventional methods, this preparation and tagging must be done separately for each individual sample being processed, a laborious process that could take several days or more for a typical validation study. The streamlined workflow and flexibility of our Access Array system addresses this critical workflow bottleneck by allowing samples from up to 48 individuals to be prepared and tagged in approximately four hours.

For example, a leading cancer research institute has utilized our Access Array system in conjunction with its next generation DNA sequencing platform to analyze key oncology genes across large cohorts of cancer samples. We believe such studies will advance the understanding of cancer etiology and potentially lead to the development of improved cancer treatments.

*Digital PCR.* We were the first to introduce and successfully commercialize a digital PCR system. Our BioMark HD and EP1 systems can be used for digital PCR, a process in which samples are partitioned into minute reaction volumes containing individual DNA strands to enable digital counting for more accurate DNA quantification. It is not practical to perform digital PCR using conventional microplate systems because they lack precision, such as in pipetting nanoliter volumes. With our systems, digital PCR has been used for a number of

different applications, including absolute quantification, determination of genomic copy number variation and detection of rare mutations. For example, pharmaceutical and biotechnology companies are taking advantage of the increased sensitivity enabled by our digital PCR technology to detect genetic mutations that are linked to drug efficacy and monitor cancer remission.

#### **Agricultural Biotechnology**

Ag-Bio customers require systems that can quickly and accurately analyze a large number of samples, such as tissue from livestock populations or seeds from a production lot, in a cost-efficient manner. The streamlined workflow of our systems allows customers to genotype a set of samples in approximately three hours as opposed to a day or more, which is the time required to prepare and run a set of samples on bead array systems. In addition, the call rate for our systems is much higher than for pre-formatted arrays or mass spectrometry, and our products offer significant cost advantages over competing systems.

For example, our BioMark system is being used to help create disease resistant strains of staple food crops for developing nations. Recently, certain genetic indicators have been identified that quickly and accurately fingerprint crops. By systematically analyzing over 300 specific genetic markers, the BioMark system is helping our customer produce and deliver seeds that will grow into plants more likely to survive, leading to improved yields. This success has led to increased adoption of the BioMark system, which is now used to selectively breed other desirable food qualities and drive agricultural efficiency and natural resource conservation.

#### **Potential Future Applications**

The inherent design flexibility of our core technology allows us to build microfluidic systems that can provide significant benefits in a wide range of fields and industries. We believe these features could lead to a number of different commercial applications including:

*Molecular Diagnostics*. Life science research is revealing additional diseases and conditions that can be diagnosed, evaluated and monitored by measuring panels of gene expression levels, SNPs, proteins or other biomarkers. Validating these research findings and translating them into clinically available tests often requires life science automation systems that are able to measure multiple biomarkers efficiently in a large number of patient samples. Our existing microfluidic systems are able to measure certain nucleic acid biomarkers that are commonly used in these tests, and in the future, we expect to develop additional systems to measure other relevant biomarkers.

We believe that the high-throughput, flexibility and simplified workflow of our microfluidic systems could make them an attractive solution for validating and commercializing a wide range of molecular diagnostic tests being developed by researchers. Our microfluidic systems have not been cleared or approved by the U.S. Food and Drug Administration, or FDA, for use in any molecular diagnostic tests and we cannot currently market them for the purpose of performing molecular diagnostic tests.

*Other Applications.* We believe that the inherent design flexibility of our core microfluidic technology allows us to perform sophisticated biochemical processes relevant to a wide range of fields and industries. We are developing our microfluidic technology for additional applications, including:

*Single-Cell Capture and Processing.* Researchers have increasingly focused on the study of single cells to better understand complex biological processes. For example, our co-founder, Dr. Stephen Quake, has used a prototype of our cell culture microfluidic chip to perform single-cell studies of cell signaling, and published these results in the journal Nature. We plan to commercially release a new system in the second half of 2012, which applies our technology to, among other things, improve single-cell analytic workflow for expression analysis.

*Protein Assays.* While the analysis of mRNA and DNA gives insight into the activity of biological systems, most biological activity in cells is carried out by proteins. We have developed a chip that allows quantitation of 18 proteins within 48 samples simultaneously. We believe that the sensitivity and specificity of this chip will be highly valuable to the life science research industry. In addition, we have demonstrated PCR-based protein quantification using commercially available reagents on our BioMark system. Although we have no immediate plans to commercialize the architectures, we believe protein assays could have an important impact on life science research.

Sample Preparation for Next Generation DNA Sequencing. In addition to the Access Array system, we have demonstrated a general architecture with the ability to use bead based purification steps in-chip, allowing sequential reactions with purification steps in between. We plan to commercially release a new system in 2013, which applies our technology to, among other things, improve single-cell analytic workflow for next generation DNA sequencing.

Our microfluidic systems address the needs of researchers and clinicians who perform mid-multiplex experimentation in the areas of genetics, Ag-Bio and molecular diagnostics. In particular, for validation studies or projects of a similar scale, our microfluidic systems substantially reduce cost, simplify workflow and increase throughput as compared to conventional microplate systems. Nevertheless, researchers may be slow to adopt our microfluidic systems as they are based on technology that, compared to conventional technology, is new and less established in the industry. Moreover, many of the existing laboratories have already made substantial capital investments in their existing systems and may be hesitant to abandon that investment. While we believe our systems provide significant cost savings, the initial price of our instruments and the price of our chips are higher than conventional systems and standard 384 well microplates. Our microfluidic systems may be more economical. In addition, for very large-scale association or survey projects, researchers may choose to use microarrays because of the ability of those products to measure thousands of genetic markers with a single device. As life science research continues to evolve and is commercialized, we believe that there will be increasing demand for life science automation solutions that enable experimentation on the scale supported by our microfluidic systems.

#### Products

We actively sell three microfluidic systems, our BioMark HD, EP1 and Access Array systems. These systems are based on one or more chips designed for particular applications and include specialized reagents, instrumentation and software. All of our systems include chip controllers that control the activation of valves and loading of reagents onto the chip. Each chip controller comes with software to control chip and instrument operations for particular applications. The BioMark HD system includes a real-time PCR machine that comprises a fast thermal cycler for PCR and a fluorescence reader that can detect the results of reactions over time. The EP1 system includes a stand-alone fast thermal cycler and an end-point fluorescence reader. The EP1 thermal cycler supports fast PCR enabling the performance of high-throughput SNP genotyping. The BioMark HD and EP1 systems both include software to analyze, annotate and archive the data produced by the reader. The Access Array system includes a stand-alone thermal cycler and two chip controllers. We provide an extensive set of protocols and application notes with all of our systems to support specific scientific applications. All of our systems are designed to be compatible with standard laboratory automation equipment.

#### The BioMark HD System

Our BioMark HD system performs high-throughput gene expression analysis, single-cell analysis, SNP genotyping and digital PCR using Fluidigm DELTAgene and SNPtype assays and other chemistries, such as TaqMan or EvaGreen.

*Fluidigm Dynamic Array Chips.* Our Fluidigm 96.96 Dynamic Array chip is based on a matrix architecture and is capable of individually assaying 96 samples against 96 reagents, generating 9,216 reactions on a single chip. Our Fluidigm 48.48 Dynamic Array chip is based on the same architecture and is capable of individually

assaying 48 samples against 48 reagents, generating 2,304 reactions. One version of each chip is optimized to perform gene expression analysis and another is optimized for genotyping. All assays are performed in volumes of 10 nanoliters or less. In 2011, we introduced our Fluidigm 192.24 Dynamic Array chip, which is capable of assaying 192 samples against 24 reagents and is particularly useful for genotyping applications that require many samples to be examined simultaneously. When used in conjunction with our BioMark HD system, our Fluidigm 192.24 Dynamic Array chip 192.24 chip provides remarkably high throughput for genotyping, allowing a researcher to generate up to 4,608 data points in one hour.

*Fluidigm Digital Array Chips*. Our Fluidigm 48.770 Digital Array chip is based on partitioning architecture that divides each of up to 48 separate samples into 770 microscopic samples and then performs a PCR or other assay for each divided sample in one nanoliter or smaller volume. Our 12.765 Digital Array chip is based on the same architecture and divides up to 12 samples into 765 parts. These chips can be used for digital PCR applications, such as rare mutation detection or copy number variation analysis.

*BioMark HD Instrumentation and Software.* Our chip controllers for the BioMark HD system fully automate the setup of Dynamic Array and Digital Array chips for real-time qPCR-based experiments and include software for implementing and tracking experiments. Our BioMark HD reader controls the PCR process and detects the fluorescent signals generated using a white light source, emission and excitation filters, precision lenses, a fast thermal cycler and a digital camera. We also offer various software packages that provide data analysis following data collection. Our analysis software shows data as a color-coded map of every position on the chip, such as for amplification curves and as numeric tabular data.

*Fluidigm DELTAgene and SNPtype Assays.* In the first half of 2011, we launched our DELTAgene and SNPtype assay products for gene expression and genotyping, respectively. These products provide optimized assays, content and services to users of our BioMark systems. They are designed to maintain the high performance standards of our BioMark systems at a substantially lower cost as compared to TaqMan-based chemistries. As a result, we are able to offer our customers an integrated genetic analysis solution that enhances the performance and efficiency of our instruments.

## The EP1 System

The EP1 system performs SNP genotyping and end-point digital PCR using Fluidigm DELTAgene and SNPtype assays and other chemistries, such as TaqMan or EvaGreen. Our EP1 system uses the same Dynamic Array and Digital Array chips that are used by our BioMark HD system. Because of its high throughput and focus on genotyping, the EP1 system is a preferred choice by our Ag-Bio customers for field implementation.

*EP1 Instrumentation and Software*. The chip controllers for the EP1 system fully automate the setup of chips for end-point SNP genotyping and digital PCR experiments, and include software for implementing and tracking experiments. Our EP1 reader detects fluorescent signals generated in our chips using a light source, emission and excitation filters, precision lenses and a digital camera. Our FC1 cycler performs fast thermal cycling for chips and enables up to 12 Dynamic Array chips to be run per day. We also offer various software packages that provide data analysis following data collection. Our analysis software shows data as color-coded map of every position on the chip, cluster maps showing results for every assay, and as numeric tabular data.

Fluidigm SNPtype Assays. Our SNPtype assay service described above is also available to users of our EP1 instruments.

#### The Access Array System

The Access Array system enables automated sample preparation, barcoding and tagging of targeted resequencing libraries, at a cost of \$10 per sample or less, for all currently marketed next generation DNA sequencers. The system is one of only a small number of high throughput target enrichment systems currently on the market that is capable of simultaneously processing multiple samples. The Access Array system can be used in conjunction with our BioMark HD system to provide real-time monitoring of amplification steps.

*Fluidigm Access Array Chips.* Our Fluidigm 48.48 Access Array chip is based on an architecture similar to that of the Dynamic Array chip, but is designed to enable recovery of reaction products from the chip. This chip combines up to 48 samples with 48 primer sets prior to PCR amplification. This is accomplished with only 96 pipetting steps as compared to approximately 7,000 pipetting steps that would be required by conventional systems. After amplification, all 48 PCR products for each sample are recovered in a pool. When PCR primers are designed to include DNA tags for specific sequencers and DNA barcodes for each sample, samples from the Access Array chip can be loaded directly into the sequencer. The DNA barcodes can then be used to identify products from each sample from the sequence data. In addition, we have shown that we have been able to combine up to ten unique primer pairs per primer set, allowing up to 480 primers per chip.

Access Array Instrumentation. The Access Array system is comprised of two chip controllers and a single stand-alone thermal cycler. This system can load Access Array chips, amplify and tag the regions of interest, and recover the sample for loading into a next generation DNA sequencer.

Access Array Primers, Barcode Libraries and Content Service. We provide optimized barcoding primers, or Access Array Barcode Libraries, for use with Roche, Life Technologies and Illumina sequencing platforms. When used with the 48.48 Access Array chip, the barcode library enables the user to pool products of different samples, perform amplification of all samples in parallel, and then sequence the pooled samples as a single sample. We also offer the Access Array Content Service to provide validated custom primer sets for users.

#### Technology

Our products are based on a tiered set of related proprietary technologies that we have either developed internally or licensed from third parties.

#### Multi-Layer Soft Lithography

Our chips are manufactured using a technology known as multi-layer soft lithography, or MSL. Using MSL technology, we are able to create valves, chambers, channels and other fluidic components on our chips at high density. We combine these components in complex arrangements that allow nanoliter quantities of fluids or drops to be precisely manipulated within the chip. Unlike most prior microfluidic technologies, our chips do not rely on electricity, magnetism or similar approaches to control fluid movement. Rather, they control fluid flow with valves. The most important components on our chips are our NanoFlex valves, which are created by the intersection of two channels on adjacent layers. When the valve is open, fluid is able to flow through the lower or flow channel. When the upper or control channel is pressurized, the material separating the two channels is deflected into the lower channel, closing the valve and stopping fluid flow. If pressure is removed from the control channel, the channels return to their original form, and the valve is again open. The elastomeric properties of microfluidic chip cores allow our NanoFlex valves to form a reliable seal and cycle through millions of openings and closings.

The elastomer we currently use for our commercial products is a form of silicone rubber known as polydimethylsiloxane, or PDMS, but we have researched other materials with different properties for specific purposes. PDMS is transparent, which allows the fluids and their contents to be easily monitored with a variety of existing optical technologies, such as bright field, phase contrast or fluorescence microscopy. The gas permeability of PDMS allows the reliable metering of fluids with near picoliter precision by eliminating the bubble problems encountered by most other microfluidic technologies: in essence, we are able to pump fluids into closed reaction chambers at sufficient pressure to drive any air out of the chamber directly through the chamber walls. This gas permeability also supports maintenance of cells in cell culture conditions. PDMS offers a favorable environment for many biochemical reactions, including PCR and cell culture.

We have developed commercial manufacturing processes to fabricate valves, channels, vias and chambers with dimensions in the ten to 100 micron range, at high density and with high yields. For research purposes, we have created devices with both substantially smaller and larger features. Though our manufacturing is based on

standard semiconductor manufacturing technologies and techniques, we have also developed novel processes for mold fabrication that enable mass production of high density chips with nanoliter volume features. These processes are sufficiently robust that new microfluidic designs can often be built using existing fabrication techniques, allowing for rapid innovation of new chip designs without needing manufacturing process or equipment changes.

#### **Microfluidic Chips**

Our chips incorporate several different types of technology that together enable us to use MSL to rapidly design and deploy new microfluidic applications.

*Microfluidic Components*. The first level of our chip technology is a library of components that perform basic microfluidic functions. We have proven designs for numerous elements, such as pumps, mixers, separation columns, control logic and reaction chambers. These are readily integrated to create circuits capable of performing a wide range of biochemical reactions. Even when it is necessary to integrate multiple elements to perform a particularly complex reaction, the area taken up on a circuit for a single reaction is small compared to our typical overall chip core size of three centimeters by three centimeters. As a result, we are routinely able to develop chips that perform thousands of reactions per square centimeter.

*Architectures*. The second level of our chip technology comprises the architectures we have designed to exploit our ability to conduct thousands of reactions on a single chip. The first of these is the Dynamic Array, a matrix architecture that allows multiple different samples and multiple different reagents to be loaded onto a single chip and then combined so that there is an isolated reaction between each sample and each reagent. The primary advantage of this architecture is that each sample and reagent is only handled by a pipette once per chip rather than once per reaction, as is the case with conventional microplate-based technologies. For example, a single 96.96 Dynamic Array chip can perform a total of 9,216 unique reactions between 96 samples and 96 reagents with only 192 pipetting steps. With conventional microplate-based technologies, the same experiment would require about 18,432 pipetting steps and at least 24 conventional microplates. In addition, the shape of the array can be changed. For instance, our 192.24 Dynamic Array chip allows reactions between 192 samples and 24 assays. Our Sample Processor architecture allows us to bring similar benefits to reactions which require export of the reaction product and more complex (multi-step) reactions. For example, our Access Array chip automates sample preparation for targeted resequencing by amplifying 48 genetic regions on each of 48 samples and exporting each prepared sample. Our Digital Array architecture allows a sample to be split into hundreds to tens of thousands of sub-samples. Separate reactions can then be conducted on each of the smaller sub-samples. Our Cell Processor architecture automates cell seeding, culture, combinatorial dosing with multiple reagents, and export for further analysis.

*Interface and Handling Frames.* The third level of our chip technology involves the interaction of our chips with the actual laboratory environment. The core elastomeric block at the center of our chip is surrounded by specially designed frames that are able to deliver samples and reagents to the blocks. These frames are the same size as standard 384 well microplates and have sample and reagent input ports laid out in a standard 384 well microplate format. As a result, our chips can be loaded with standard laboratory pipetting robots and can be used with standard plate handling equipment. These frames also transmit the pressure and control signals from our instruments to the chip.

*Technological Advances.* Our 48.770 Digital Array chips have over 4,000 valves capable of more than 4,000 assays per square centimeter, a 181-fold increase in valve density and a 1,600-fold increase in assay capability as compared to the first prototype of our 1.48 chip sold in 2002. In our research and development laboratory, we have built and tested fully functional Digital Array chips capable of performing 200,000 assays, over five-fold more than our 48.770 Digital Array chip. We have also developed the capability to capture many single cells from a flow stream, as well as to conduct molecular biology protocols on each individual cell in parallel. We are applying this capability to integrate automated cell capture and specific target amplification.

We have added capabilities to our chips in addition to increasing the density. In 2009, we elaborated our 48.48 chip architecture to enable the recovery of DNA samples from reaction chambers after PCR amplification. The elaborated chips are now sold as part of the Access Array system, which allows the high-throughput preparation of samples for next-generation DNA sequencing.

We also recently developed a second generation interface technology, which increases our number of chip control signals, or states, by nearly a factor of 10 (from 4 to 36). Since the number of chip states is approximately 2 raised to the power of the number of control signals, this represents a billion-fold increase in the number of states a chip may be set to; this advance means that the complexity of reactions that our chips may run is no longer meaningfully limited by the number of control lines. This architecture was implemented on commercial products in 2011.

#### Software and Instrumentation

We have developed instrumentation technology to load samples and reagents onto our chips and to control and monitor reactions within our chips. Our line of chip controllers consists of commercial pneumatic components and both custom and commercial electronics. They apply precise control of multiple pressures to move fluid and control valve states in an microfluidic chip. Our BioMark HD system consists of a custom fast thermal cycler packaged with a sophisticated fluorescence imaging system. Our FC1 cycler is a custom thermal cycler capable of very rapid cycling: 45 cycles in 30 minutes. Our EP1 instrument is a fluorescence reader designed for endpoint imaging, suitable for genotyping and digital PCR applications. All of these instruments are designed to be easily introduced into standard automated lab environments.

We have developed specialized software to manage and analyze the unusually large amounts of data produced by our systems. Our BioMark HD system s gene expression analysis software automatically measures individual real-time qPCR reactions from fluorescent images and generates amplification threshold crossing values allowing researchers to readily perform complete normalized comparative gene expression analysis across large numbers of samples and assays. Similarly, our SNP Genotyping Analysis software automatically clusters fluorescent intensities from individual genotype reactions and makes genotype calls across individual and multiple chip runs. The Digital PCR Analysis software automatically calculates absolute copy number and copy number ratios from digital PCR experiments. Our Melting Curve Analysis software supports genotyping from data collected on the BioMark HD reader.

#### Protocols and Assays Design

We provide protocols to guide our customers in the use our products with commonly available molecular biology reagents for the analysis of their specific sample types. The set of protocols we offer are regularly expanded. For gene expression, we currently provide a protocol for TaqMan real-time reagents for general gene expression analysis. We also offer a protocol specifically for single-cell analysis. In early 2010 we released a protocol for EvaGreen, a DNA binding dye for gene expression measurements with excellent data quality and a very low cost per assay. We also released protocols for the use of our microfluidic systems with Thermo-Fisher Solaris assays. PCR assay reagents need to be specific to The gene targets of interest. Since our systems analyze many gene targets at once, the process of designing a set of assays may delay the implementation experiments or require the use of expensive pre-designed assays. To address this issue we have developed a computational method for rapid-turn PCR assay design. This process allows us to provide customers with validated assays for their targets of interest. We have commercialized this service for our BioMark HD, EP1 and Access Array customers through the launch of our DELTAgene and SNPtype assays and our Access Array Target-Specific primers.

In the first quarter of 2011, we introduced our DELTAgene assay product, consisting of assay design and custom content delivery systems for gene expression, that allow customers to specify genes of interest and match them to region-specific primers and enables our existing systems to amplify specific genetic regions of interest. In the second quarter of 2011, we introduced a similar assay design and custom content delivery system for

genotyping called SNPtype. We believe these assay design and content delivery systems represent an improvement over conventional pre-defined panels by allowing customization based on cellular pathways or biological areas of interest while lowering up-front costs of experiments. These offerings provide low-cost alternatives to chemistries such as TaqMan and allow customers to use chips in more flexible ways. By specifying genes or SNP sites of interest and matching them to region specific primers, customers using our existing systems are able to amplify specific genetic regions of interest at reduced cost without sacrificing data quality.

#### Sales and Marketing

We distribute our microfluidic systems through our direct sales force and support organizations located in North America, Europe and Asia-Pacific, and through distributors or sales agents in several European, Latin American, Middle Eastern and Asia-Pacific countries. Our domestic and international sales force informs our current and potential customers of current product offerings, new product introductions, technological advances in our microfluidic systems and workflows, and notable research being performed by our customers or ourselves. As our primary point of contact in the marketplace, our sales force focuses on delivering a consistent marketing message and high level of customer service, while also attempting to help us better understand our customer needs. As of December 31, 2011, we had 72 people employed in sales, sales and technical support and marketing, including 42 sales representatives and technical pre-sales specialists located in the field. We intend to significantly expand our sales, support and marketing efforts in the future.

Our sales and marketing efforts are targeted at laboratory directors and principal investigators at leading companies and institutions who need reliable life science automation solutions for their business or commercial purposes. We seek to increase awareness of our products among our target customers through regular contact, participation in tradeshows, on customer site seminars, academic conferences and dedicated company gatherings attended by prominent users and prospective customers from various institutions.

Our systems are relatively new to the market place and require a capital investment. As a result our sales process often involves numerous interactions and demonstrations with multiple people within an organization. Some potential customers conduct in-depth evaluations of the system including running experiments on our system and competing systems. In addition, in most countries, sales to academic or governmental institutions require participation in a tender process involving preparation of extensive documentation and a lengthy review process. As a result of these factors and the budget cycles of our customers, our sales cycle, the time from initial contact with a customer to our receipt of a purchase order, can often be 12 months or longer.

#### **Commercial Alliances**

#### **Co-Marketing Agreements for Next Generation Sequencing**

We have entered into an agreement to co-market our Access Array system with 454 Life Sciences, a division of F. Hoffman-La Roche Ltd., a manufacturer of leading next generation DNA sequencing platforms. Per our agreement, we may bundle our Access Array sample preparation system with our co-marketer s next generation DNA sequencing technologies. This agreement enables us to, among other things, engage in co-operative marketing and messaging, perform selective specialization or utilization of our co-marketer s channel for promotional or sales activity, and educate our direct and indirect distribution channels, in each case without any minimum sales, volume or other financial obligations. The agreement does not preclude us from engaging in other activities of similar or related interest with other participants in the sequencing technology market and may be terminated by either party with notice. We have entered into a similar co-marketing agreement with another manufacturer of next generation DNA sequencing platforms. This second agreement is in its early stages, does not contain any minimum performance obligations of the parties and may be terminated at anytime by either party with notice.

#### Non-invasive Prenatal Diagnostics Collaboration

We entered into a set of related agreements with Novartis V&D, in May 2010 which were subsequently amended in March 2011. Under these agreements, our capabilities in digital PCR are being developed for potential in-vitro diagnostics applications, with an initial focus on the development of an NIPD test for fetal aneuploidies. These agreements provide Novartis V&D with an option to exclusively license our technology in the primary field of non-invasive testing for fetal aneuploidies and the secondary field of non-invasive testing of genetic abnormality, disease or condition in a fetus or in a pregnant woman (other than as tested in the primary field), RhD genotyping or carrier status in a pregnant woman and the genetic carrier status of a prospective mother and her male partner. Under these agreements, except with Novartis V&D, we cannot, directly or in collaboration with a third party, use, develop or sell any products or services in the primary field or the secondary field, other than for research applications in the secondary field. We have achieved our initial technical feasibility milestones in 2011 and received milestone payments totaling \$3.3 million.

At Novartis V&D s option, these agreements can be extended to encompass further research, development and commercialization of our products in the primary and secondary fields described above, which could take several years or more to complete. If the agreements are extended, we will negotiate additional technical feasibility milestones and milestone payments with Novartis V&D. In addition, the agreements provide for payments to us upon Novartis V&D s exercise of its option to license our technology and upon our meeting a specified product development milestone. These additional payments potentially total \$3.0 million if these agreements are extended. The term of the development portion of the agreements will extend until attainment of all existing and to-be-negotiated technical feasibility milestones, but will automatically terminate if Novartis V&D does not exercise its option to license our technology by April 30, 2012. In addition, the agreements may be terminated at any time in Novartis V&D s sole discretion and, by us, at certain times, if Novartis V&D elects not to proceed with the development program. The agreements provide that if a test is commercialized, we would supply the required systems and chips for performance of such test.

#### Single-Cell Genomics Collaboration

In August 2011, we entered into an agreement to collaborate with BD Biosciences, a segment of Becton, Dickinson and Company, or BD, with respect to single-cell genomics. Pursuant to this agreement, we and BD will jointly make a series of public presentations describing the significant scientific insights obtainable by combining the ability of BD s instruments to measure multiple surface markers of an individual cell with our systems ability to measure hundreds of genes from the same cell.

#### Customers

We have sold our BioMark, EP1 and Access Array systems to leading academic institutions, diagnostic laboratories, and pharmaceutical, biotechnology and Ag-Bio companies. We have sold over 500 systems to customers in over 25 countries. No single customer represented more than 10% of our total revenue for 2011, 2010 and 2009.

#### Manufacturing

Our microfluidic systems and instrumentation for commercial sale, as well as for internal research and development purposes, are manufactured at our facilities in Singapore. We also manufacture assays and chips for research and development at our headquarters in South San Francisco, California.

We established our primary manufacturing facility in Singapore to take advantage of the skilled workforce, supplier and partner network, lower operating costs and government support available there. Our microfluidic system manufacturing process includes photolithography and fabrication technologies that are very similar to those used in the fabrication of semiconductor chips. As a result, we are able to hire from a pool of skilled manpower created by the existing semiconductor industry in Singapore. Similarly, the Singapore semiconductor

industry has created a broad network of potential suppliers and partners for our manufacturing operations. We are able to locally source a large proportion of the raw materials required in our processes and have been able to collaborate with local engineering companies to develop enabling technologies chip fabrication.

Our manufacturing operations in Singapore have been supported by grants from the Singapore Economic Development Board, or EDB, which provides incentive grant payments for research, development and manufacturing activity in Singapore. Our arrangements with EDB require us to maintain a significant and increasing manufacturing and research and development presence in Singapore.

We expect that our existing manufacturing capacity for instrumentation and chips is sufficient to meet our needs at least through 2013. However, we are considering developing additional capacity to ensure that all or most of our products are produced by at least two different facilities. We believe that having dual sources for our products would help mitigate the potential impact of a production disruption at any one of our facilities and that such redundancy may be required by our customers in the future. We have not determined the timing or location of any additional manufacturing capacity.

We rely on a limited number of suppliers for certain components and materials used in our products. While we are in the process of qualifying additional sources of supply, we cannot predict how long that qualification process will last. If we were to lose one or more of our limited source suppliers, it would take significant time and effort to qualify alternative suppliers. Key components in our products that are supplied by sole or limited source suppliers include a specialized polymer from which our chip cores are fabricated, specialized custom camera lenses, fiberlight guides and other components required for the reader of our BioMark system, and certain raw materials for our DELTAgene and SNPtype assays and Access Array Target-Specific primers. With respect to many of our suppliers, we are neither a major customer, nor do we have long term supply contracts. These suppliers may therefore give other customers needs higher priority than ours, and we may not be able to obtain adequate supply in a timely manner or on commercially reasonable terms.

#### **Research and Development**

We have assembled experienced research and development teams at our South San Francisco and Singapore locations with the scientific, engineering, software, bioinformatic and process talent that we believe is required to grow our business.

#### New Product and Application Development

The largest component of our current research and development effort is in the areas of new products and new applications. We plan to introduce a new platform for single-cell capture and preparation with capability to support a variety of analytical methods, and to strengthen our current product lines by further simplifying the workflows.

*Single-Cell Analysis Tools.* We intend to strengthen the single-cell analysis capability of our BioMark system by expanding our customers options for single-cell capture, manipulation and downstream data analysis. For example, we are developing a system for single-cell capture and preparation that will increase the types of samples that can be processed routinely, as well as the types of usable preparation chemistry. We expect that this new system will be able to prepare samples both for BioMark systems, as well as for next generation sequencing.

*Cell Culture System.* With the support of a grant from the California Institute of Regenerative Medicine, or CIRM, in an aggregate amount of \$750,000, we have developed a prototype microfluidic cell culture system that enables researchers to independently control the conditions for multiple cell cultures, allowing sequential dosing of a variety of factors and then extraction of the cells for further analysis. CIRM has awarded us with an additional \$1.9 million grant over three years to further advance research in this area and to deliver useable prototypes to a limited number of stem cell research laboratories.

Assay and Reagent Development. We intend to enhance our SNPtype genotyping assays, DELTAgene gene expression assays, and Access Array Target-Specific primer sets with improved performance and features. For genotyping, we plan to improve our SNPtype bioinformatic pipelines to support additional types of mutations, improve assay design rates for difficult areas of the genome, and offer it in additional formats. For gene expression, we intend to lower sample preparation reagents with lower costs and to increase the multiplexing to enable analysis of larger sets of genes. For the growing number of new third party commercial sequencing platforms, we plan to provide reagents necessary to support Access Array Target-Specific primer sets for a wider variety of platforms.

*Integrated Fluidic Circuit and Instrument Architectures.* We intend to develop additional products to strengthen the capabilities of our existing Dynamic Array and Digital Array product families. For example, our existing 48.770 Digital Array chip can perform 36,960 reactions. We have developed prototype chips based on the Digital Array architecture that can perform 200,000 or more reactions. We intend to design Dynamic Array architectures that are more flexible and cost effective for researchers with smaller numbers of assays or smaller numbers of samples. We plan to evaluate next generation instruments architectures supporting these new chip formats for our existing markets and with features potentially suitable for clinical markets.

#### **Process Development**

The second component of our research and development effort is process development. We continuously develop new manufacturing processes and test methods to drive down manufacturing cost, increase manufacturing throughput, widen fabrication process capability, and support new microfluidic devices and designs. Our prototype fabrication facility at our Singapore manufacturer fabricates prototype chips working closely with product development teams in South San Francisco, California. This process development team s focus is to improve fabrication processes for the production line. We invest in manufacturing automation, process changes and design modifications which historically have significantly improved yields and lowered the manufacturing costs of our chips.

#### New Technology Development

We have background research and development efforts to increase the density of components on our microfluidic systems and to lower the materials cost of our current production methods. We are evaluating new materials that can increase the functionality of existing products and that would allow our microfluidic systems to be used for a wider variety of biological and chemical reactions. Over the longer term, we are seeking ways to transfer functionality from instrumentation to chips to support development of field-based and point-of-care applications.

Our research and development expenses were \$13.9 million, \$13.0 million and \$12.3 million in 2011, 2010 and 2009, respectively. As of December 31, 2011, 60 of our employees were engaged in research and development activities.

#### Competition

We compete with both established and development stage life science companies that design, manufacture and market instruments for gene expression analysis, genotyping, other nucleic acid detection and additional applications. For example, companies such as Affymetrix, Inc., Agilent Technologies, Inc., Bio-Rad Laboratories, Inc., Illumina, Inc., Life Technologies Corporation, LGC Limited, Luminex Corporation, NanoString Technologies, Inc., PerkinElmer, Inc. (through its acquisition of Caliper Life Sciences, Inc.), RainDance Technologies, Inc., Roche Applied Science (a division of Roche Diagnostics Corporation), Sequenom, Inc. and WaferGen Bio-Systems, Inc. have products that compete in certain segments of the market in which we sell our products. In addition, a number of other companies and academic groups are in the process of developing novel technologies for life science markets.

The life science automation industry is highly competitive and expected to grow more competitive with the increasing knowledge gained from ongoing research and development. Many of our competitors are either publicly traded or are divisions of publicly traded companies and enjoy several competitive advantages over us, including:

significantly greater name recognition;

greater financial and human resources;

broader product lines and product packages;

larger sales forces;

larger and more geographically dispersed customer support organization;

substantial intellectual property portfolios;

larger and more established customer bases and relationships;

greater resources dedicated to marketing efforts;

better established and larger scale manufacturing capability; and

greater resources and longer experience in research and development. We believe that the principal competitive factors in our target markets include:

cost of capital equipment and supplies;

reputation among customers;

innovation in product offerings;

flexibility and ease of use;

accuracy and reproducibility of results; and

## Edgar Filing: FLUIDIGM CORP - Form 10-K

#### compatibility with existing laboratory processes, tools and methods.

To successfully compete with existing products and future technologies, we need to demonstrate to potential customers that the cost savings and performance of our technologies and products, as well as our customer support capabilities, are superior to those of our competitors. The regular introduction of new and innovative offerings is necessary to continue to differentiate our company from other, larger enterprises. Additionally, a well staffed commercial team in the field is required to successfully communicate the advantages of our products and overcome potential obstacles acceptance of our products. In addition ongoing collaborations and partnerships with key opinion leaders in the genetics fields are desirable to demonstrate both innovation and applicability of our products. These relationships create the need for retention of a large and talented specialized staff, and occasionally require the placement of products or supplies on a temporary basis at a customer facility to demonstrate applicability of our tool to a specific scientific application.

#### **Intellectual Property**

#### Strategy and Position

Our core technology originated at the California Institute of Technology, or Caltech, in the laboratory of Professor Stephen Quake, who is a co-founder of Fluidigm. Dr. Quake, his students and their collaborators pioneered the application of multilayer soft lithography in the field of microfluidics. In particular, Dr. Quake s laboratory developed technologies that enabled the production of specialized valves and pumps capable of controlling fluid flow at nanoliter volumes. In a series of transactions, we exclusively licensed from Caltech the relevant patent filings relating to these developments. We have also entered into additional exclusive and non-exclusive licenses for related technologies from various companies and academic institutions.

Our patent strategy is to seek broad patent protection on new developments in microfluidic technology and then later file patent applications covering new implementations of the technology and new microfluidic circuit architectures utilizing the technology. As these technologies are implemented and tested, we file new patent applications covering scientific methodology enabled by our technology. Additionally, where appropriate, we file new patent applications covering instrumentation and software that are used in conjunction with our microfluidic systems.

We have developed our own portfolio of issued patents and patent applications directed to commercial products and technologies in development. Our portfolio covers methods and devices for isolating, culturing, and analyzing single cells; technologies for processing and preparing DNA samples for next generation DNA sequencing; high-density and reusable chips for performing genotyping and measuring gene expression with massive multiplexing, and techniques for using these chips; and associated instrumentation and software for controlling and reading our chips and analyzing the data obtained from them. We also have 36 patents and patent applications pending relating to devices, techniques and applications for digital PCR, including methodologies for measuring copy number variation and noninvasively diagnosing prenatal genetic abnormalities.

As of December 31, 2011, we owned or licensed over 200 patents, most of which issued in the United States, and we had approximately 250 pending patent applications worldwide, including approximately 100 in the United States. Our patents have expiration dates ranging from 2018 to 2030. The U.S. issued patents we have licensed from Caltech expire between 2017 and 2026; the U.S. issued patents we have licensed from other parties expire between 2019 and 2027.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. Our patents may not enable us to obtain or keep any competitive advantage. Our pending U.S. and foreign patent applications may not issue as patents or may not issue in a form that will be advantageous to us. Any patents we have obtained or do obtain may be challenged by re-examination, opposition or other administrative proceeding, or may be challenged in litigation, and such challenges could result in a determination that the patent is invalid. In addition, competitors may be able to design alternative methods or devices that avoid infringement of our patents. To the extent our intellectual property protection offers inadequate protection, or is found to be invalid, we are exposed to a greater risk of direct competition. If our intellectual property does not provide adequate protection against our competitors products, our competitive position could be adversely affected, as could our business. Both the patent application process and the process of managing patent disputes can be time consuming and expensive. Furthermore, the laws of some foreign countries may not protect our intellectual property rights to the same extent as do the laws of the United States.

In addition to pursuing patents on our technology, we have taken steps to protect our intellectual property and proprietary technology by entering into confidentiality agreements and intellectual property assignment agreements with our employees, consultants, corporate partners and, when needed, our advisors. Such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements, and we may not be able to prevent such unauthorized disclosure. Monitoring unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate.

Our commercial success may depend in part on our non-infringement of the patents or proprietary rights of third parties. Third parties have asserted and may assert in the future that we are employing their proprietary technology without authorization. Competitors may assert that our products infringe their intellectual property rights as part of a business strategy to impede our successful entry into those markets. In addition, our competitors and others may have patents or may in the future obtain patents and claim that use of our products infringes these patents. We could incur substantial costs and divert the attention of our management and technical personnel in defending against any of these claims. Parties making claims against us may be able to obtain injunctive or other relief, which could block our ability to develop, commercialize and sell products, and could

result in the award of substantial damages against us. In the event of a successful claim of infringement against us, we may be required to pay damages and obtain one or more licenses from third parties, or be prohibited from selling certain products. We may not be able to obtain these licenses at a reasonable cost, if at all.

#### License Agreements

We have entered into several significant exclusive, co-exclusive, and non-exclusive licenses to patents and patent applications owned by various academic institutions and have additional intellectual property agreements with a range of institutions and companies.

Our license agreement with Caltech provides us with an exclusive, worldwide license to certain patents and related intellectual property, as well as the right to prosecute licensed patent filings worldwide at our expense and to initiate any infringement proceedings. Caltech retains the right to use the licensed materials for noncommercial educational and research purposes, as well as any rights necessary to comply with the statutory rights of the U.S. government. We have issued shares of our common stock to Caltech and we agreed to pay to Caltech royalties based on sales revenue of licensed products on a country-by-country basis with a minimum annual royalty. The license agreement will terminate as to each country and licensed product upon expiration of the last-to-expire patent covering licensed products in each country.

Our license agreements with Harvard University allow sublicenses (i) provided we can demonstrate that we have added significant value to the patent rights to be sublicensed and that such sublicense also contains a substantial and essentially simultaneous license to intellectual property owned by us, or (ii) when such patent rights are necessary to practice other Harvard University patent rights exclusively licensed to us which are also being licensed. We have issued shares of our common stock to Harvard and we agreed to pay to Harvard royalties based on sales revenue of licensed products on a country-by-country basis with a minimum annual royalty. Harvard is responsible for filing and maintaining all licensed patents, but we must reimburse Harvard for our share of its related patent prosecution expenses. We have the right to prosecute any infringement of our licensed patent rights. The license agreement will terminate with the last-to-expire of the licensed patents.

On June 30, 2011, we settled certain litigation and entered into a series of patent cross-license and sub-license agreements with Life Technologies Corporation and its Applied Biosystems, LLC subsidiary, referred to as Life, relating to various patent rights of the two companies. Specifically, the agreements involve a cross-license concerning our imaging readers and other patent filings and certain of Life s patent families relating to methods and instruments for conducting nucleic acid amplification, such as with PCR; a sub-license that provides us access to certain of Life s digital PCR patents; and a sublicense that provides Life access to certain of our non-core technology patents licensed from the California Institute of Technology. These agreements resolve litigation filed by us against Life in June 2011 in U.S. District Court for the Northern District of California and by Life against us in June 2011 in U.S. District Court for the District of Delaware. Under the terms of the agreements, each party is responsible for making certain payments to the other, and in June 2011, these obligations resulted in a net \$3.0 million payment to Life from us. We expensed the \$3.0 million and classified it as litigation settlement in our June 30, 2011 condensed consolidated statement of operations because the agreement specified that the amount paid by us was principally attributable to resolving Life s litigation claims with respect to a specific expiring U.S. patent and its foreign counterparts. The agreements also provide for various royalty payments by each of the parties, including a royalty on certain Life instruments.

Under the terms of the agreements, either party had the option, exercisable for 30 days from the date of the agreements, to limit or preclude certain patent litigation between the parties over the next two to four years. These rights were subject to certain exceptions and would involve an additional payment by the respective party exercising the option at the time of exercise. In July 2011, we exercised our option and paid Life \$2.0 million. As a result, subject to certain exceptions, Life may not initiate litigation under its patents existing as of June 30, 2011 against our customer s for two years and against our company, with respect to our current products and equivalent future products, for four years. The additional payment was recorded in other assets and amortized to selling, general and administrative expense over four years on a straight-line basis beginning in July 2011. The

additional payment is being amortized to selling, general and administrative expense because it precludes Life from initiating litigation under its relevant patents for any alleged prior and future infringement by us for four years, and because such preclusion relates to our equivalent future products. Life elected not to exercise its option.

In May 2011, we entered into a license agreement with Caliper Life Sciences, Inc., which subsequently became a PerkinElmer company, referred to as Caliper, to license Caliper's existing patent portfolio in certain fields, including non-invasive prenatal diagnostics, and obtained an option to extend the license to cover additional fields. Under the agreement, we made an up-front payment of \$625,000, which is subject to adjustment, and will have royalty obligations commencing in January 2012. In August 2011, we entered into an amendment to the agreement with Caliper and made an additional up-front payment of \$0.5 million. Pursuant to the amendment, the rates for royalties payable to Caliper were substantially reduced and the period for which we are obligated to make royalty payments was shortened, with the last payment due in mid-2018 for our existing products at the time of amendment and their future equivalents. If any of our future products are determined to infringe Caliper's patents, the same reduced royalty rates will apply until the respective patents expire. The aggregate \$1.1 million of payments to Caliper are being amortized to cost of product revenue on a straight-line basis through July 2018, when our royalty payment obligations are expected to terminate based upon our current products. Our royalty payments are not expected to be material to our company in future periods.

#### **Government Regulation**

Pursuant to its authority under the Federal Food, Drug and Cosmetic Act, or FFDCA, FDA has jurisdiction over medical devices, which are defined to include, among other things, in vitro diagnostic products, or IVDs. Our products are currently labeled and sold for research purposes only, and we sell them to academic institutions, life sciences laboratories, and pharmaceutical and biotechnology companies for non-diagnostic purposes. Because our products are not intended for use in clinical practice in the diagnosis of disease or other conditions, they do not fit the definition of a medical device under the FFDCA and thus are not subject to regulation by the FDA, as medical devices. In particular, while FDA regulations require that research only products be labeled. For Research Use Only. Not for use in diagnostic procedures , the regulations do not subject such products to FDA s pre- and post-market controls for medical devices. In June 2011 the FDA issued a draft guidance document intended to clarify the types of in vitro diagnostic products that are properly labeled for research use only. The draft guidance states that merely including a labeling statement that the product is for research purposes only will not necessarily render the device exempt from the FDA s clearance, approval, or other requirements if the circumstances surrounding the distribution of the product indicate that the manufacturer knows its product is being used by customers for diagnostic uses. These circumstances may include written or verbal marketing claims regarding a product s performance in clinical applications and a manufacturer s provision of technical support for such activities. In the future, certain of our products or related applications could become subject to regulation as medical devices by FDA.

For example, if we wish to label and market our products for use in performing clinical diagnostics, thus subjecting them to regulation by FDA as medical devices, unless an exemption applies, we would be required to obtain either prior 510(k) clearance or prior pre-market approval from the FDA before commercializing the product. The FDA classifies medical devices into one of three classes. Devices deemed to pose lower risk to the patient are placed in either class I or II, which, unless an exemption applies, requires the manufacturer to submit a pre-market notification requesting FDA clearance for commercial distribution pursuant to Section 510(k) of the FFDCA. This process, known as 510(k) clearance, requires that the manufacturer demonstrate that the device is substantially equivalent to a previously cleared and legally marketed 510(k) device or a pre-amendment class III device for which pre-market approval applications, or PMAs, have not been required by the FDA. This process deemed by FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or those deemed not substantially equivalent to a legally marketed predicate device, are placed in class III devices typically require PMA approval. To obtain PMA approval, an

applicant must demonstrate the reasonable safety and effectiveness of the device based, in part, on data obtained in clinical studies. PMA reviews generally last between one and two years, although they can take longer. Both the 510(k) and the PMA processes can be expensive and lengthy and may not result in clearance or approval. If we are required to submit our products for pre-market review by the FDA, we may be required to delay marketing while we obtain premarket clearance or approval from the FDA. There would be no assurance that we could ever obtain such clearance or approval.

Changes to a device that have received PMA approval typically require a new PMA or PMA supplement. Changes to a device that received 510(k) clearance which could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, require a new 510(k) clearance or possibly PMA approval. The FDA requires each manufacturer to make this determination initially, but the FDA can review any of these decisions and may disagree. If the FDA disagreed with our determination not to seek a new 510(k) clearance for a change to a previously marketed product, the FDA could require us to seek a new 510(k) clearance or pre-market approval. The FDA also could require us to cease manufacturing and/or recall the modified device until 510(k) clearance or pre-market approval was obtained. Also, in these circumstances, we could be subject to warning letters, adverse publicity, significant regulatory fines or penalties, seizure or injunctive action, or criminal prosecution.

In some cases, our customers or collaborators may use our products in their own laboratory-developed tests, or LDTs, or in other FDA-regulated products for clinical diagnostic use. The FDA has historically exercised enforcement discretion in not enforcing the medical device regulations against LDTs. However, the FDA could assert jurisdiction over some or all LDTs, which may impact our customers uses of our products or the sale of our products for LDT uses. A significant change in the way that the FDA regulates our products or the LDTs that our customers develop may require us to change our business model in order to maintain compliance with these laws. The FDA recently held a meeting in July 2010, during which it indicated that it intends to reconsider its policy of enforcement discretion and to begin drafting a new oversight framework for LDTs.

We are collaborating with Novartis V&D to develop products to target the NIPD market for fetal aneuploidies. Our product development is in its early stages and we have not made any submissions to the FDA regarding the products or determined whether FDA clearance or approval will be required.

If our products become subject to regulation as a medical device, we would become subject to additional FDA requirements, and we could be subject to unannounced inspections by FDA and other governmental authorities, which could increase our costs of doing business. Specifically, manufacturers of medical devices must comply with various requirements of the FFDCA and its implementing regulations, including:

the Quality System Regulation, which covers the methods and documentation of the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of our product;

labeling regulations;

medical device reporting, or MDR, regulations;

correction and removal regulations; and

post-market surveillance regulations, which include restrictions on marketing and promotion. We would need to continue to invest significant time and other resources to ensure ongoing compliance with FDA quality system regulations and other post-market regulatory requirements.

Our failure to comply with applicable FDA regulatory requirements, or our failure to timely and adequately respond to inspectional observations, could result in enforcement action by the FDA, which may include the following sanctions:

## Edgar Filing: FLUIDIGM CORP - Form 10-K

fines, injunctions and civil penalties;

recall or seizure or our products;

operating restrictions, partial suspension or total shutdown of production;

delays in clearance or approval, or failure to obtain approval or clearance of future product candidates or product modifications;

restrictions on labeling and promotion;

adverse publicity, warning letters, fines, or injunctions;

withdrawal of previously granted clearances or approvals; and

#### criminal prosecution.

International sales of medical devices are subject to foreign government regulations, which vary substantially from country to country. The primary regulatory environment in Europe is that of the European Union, or EU, which includes most of the major countries in Europe. Currently, 27 countries make up the EU. Other countries, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the EU with respect to medical devices. The EU has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear the CE conformity marking, indicating that the device conforms to the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout Europe. Outside of the EU, regulatory approval needs to be sought on a country-by-country basis in order to market medical devices. Although there is a trend towards harmonization of quality system standards, regulations in each country may vary substantially which can affect timelines of introduction.

#### **Property and Environmental Matters**

We lease approximately 30,000 square feet of office and laboratory space at our headquarters in South San Francisco, California under a lease that expires in April 2015, approximately 28,000 square feet of manufacturing and office space at our facility in Singapore under leases with varying expiration dates through October 2014. In addition, we lease office space in Paris, France on a month-to-month basis; in Tokyo, Japan under a lease that expires in November 2013; in Osaka, Japan under a lease that expires in September 2012; and in Shanghai, China under a lease that expires in May 2013. We believe that our existing office, laboratory and manufacturing space, together with additional space and facilities available on commercially reasonable terms, will be sufficient to meet our needs through 2013.

Our research and development and manufacturing processes involve the controlled use of hazardous materials, including flammables, toxics, corrosives and biologics. Our research and manufacturing operations produce hazardous biological and chemical waste products. We seek to comply with applicable laws regarding the handling and disposal of such materials. Given the small volume of such materials used or generated at our facilities, we do not expect our compliance efforts to have a material effect on our capital expenditures, earnings and competitive position. However, we cannot eliminate the risk of accidental contamination or discharge and any resultant injury from these materials. We do not currently maintain separate environmental liability coverage and any such contamination or discharge could result in significant cost to us in penalties, damages and suspension of our operations.

#### **Geographic Information**

During the last three years, a majority of our revenue was generated within North America and Europe and a majority of our long-lived assets are located within the United States and Singapore. Please see Note 15 of the notes to our audited consolidated financial statements for additional information for geographic areas.

#### Seasonality

In 2008, 2009 and 2010, our product revenue was higher in the fourth quarter of the year than in the first quarter of the next year reflecting numerous factors, including, among others, seasonal variations in customer operations and customer budget and capital spending cycles.

## Edgar Filing: FLUIDIGM CORP - Form 10-K

#### Employees

As of December 31, 2011, we had 239 employees, of which 60 work in research and development, 40 work in general and administrative, 67 work in manufacturing, 72 work in sales, sales and technical support and marketing. None of our employees are represented by a labor union or are the subject of a collective bargaining agreement.

## **Executive** Officers

The following table sets forth the names, ages (as of February 29, 2012) and positions of our executive officers:

Name	Age	Position
Gajus V. Worthington		President, Chief Executive Officer and Director
Vikram Jog	55	Chief Financial Officer
Robert C. Jones	57	Executive Vice President, Research and Development
William M. Smith	60	Executive Vice President, Legal Affairs, General Counsel and Secretary
Fredric Walder	54	Chief Business Officer
Mai Chan (Grace) Yow	53	Executive Vice President, Worldwide Manufacturing and Managing
		Director of Fluidigm Singapore Pte. Ltd.

*Gajus V. Worthington* is a co-founder of Fluidigm and has served as our President and Chief Executive Officer and a Director since our inception in June 1999. From May 1994 to April 1999, Mr. Worthington held various staff and management positions at Actel Corporation, a public semiconductor corporation that was sold to Microsemi Corporation in 2010. Mr. Worthington received a B.S. in Physics and an M.S. in Electrical Engineering from Stanford University.

*Vikram Jog* has served as our Chief Financial Officer since February 2008. From April 2005 to February 2008, Mr. Jog served as Chief Financial Officer for XDx, Inc., a molecular diagnostics company. From March 2003 to April 2005, Mr. Jog was a Vice President of Applera Corporation, a life science company that is now part of Life Technologies, Inc., and Vice President of Finance for its related businesses, Celera Genomics and Celera Diagnostics. From April 2001 to March 2003, Mr. Jog was Vice President of Finance for Celera Diagnostics and Corporate Controller of Applera Corporation. Mr. Jog received a Bachelor of Commerce degree from Delhi University and an M.B.A. from Temple University. Mr. Jog is a member of the American Institute of Certified Public Accountants.

*Robert C. Jones* has served as our Executive Vice President, Research and Development since August 2005. From August 1984 to July 2005, Mr. Jones held various managerial and research and development positions at Applied Biosystems, a laboratory equipment and supplies manufacturer that was a division of Applera Corporation, including: Senior Vice President Research and Development from April 2001 to August 2005; Vice President and General Manager Informatics Division from 1998 to 2001; and Vice President PCR Business Unit from 1994 to 1998. Mr. Jones received a BSEE in Electrical Engineering and an MSEE in Computer Engineering from the University of Washington.

*William M. Smith* has served as our Executive Vice President, Legal Affairs since January 2012 and as General Counsel and our Secretary since May 2000. From May 2000 to January 2012, Mr. Smith served as our Vice President, Legal Affairs and served as a Director from May 2000 to April 2008. Mr. Smith served as an associate and then as a partner at the law firm of Townsend and Townsend and Crew, LLP from 1985 through April 2008. Mr. Smith received a J.D. and an M.P.A. from the University of Southern California and a B.A. in Biology from the University of California, San Diego.

*Fredric Walder* has served as our Chief Business Officer since May 2010. From August 1992 to April 2010 he served in various senior executive positions at Thermo Fisher Scientific Inc., a laboratory equipment and

supplies manufacturer, including as Senior Vice President, Customer Excellence from November 2006 to April 2010 and Division President, Thermo Electron Corporation from January 2000 to November 2006. Mr. Walder holds a B.S. in Chemistry from the University of Massachusetts.

*Mai Chan (Grace) Yow* has served as Executive Vice President, Worldwide Manufacturing of Fluidigm Singapore Pte. Ltd., our Singapore subsidiary, since January 2012 and as Managing Director of Fluidigm Singapore Pte. Ltd. since March 2006. Ms. Yow served as Vice President, Worldwide Manufacturing, from March 2006 to January 2012. From June 2005 to March 2006, Ms. Yow served as General Manager of Fluidigm Singapore Pte. Ltd. From August 2004 to May 2005, Ms. Yow served as Vice President Engineering (Asia) for Kulicke and Soffa, a public semiconductor equipment manufacturer. From March 1991 to July 2004, Ms. Yow served as Director, Assembly Operations, Plant Facilities and EHS, for National Semiconductor Singapore, a semiconductor fabrication subsidiary of National Semiconductor Corporation. Ms. Yow received a B.E. in Electronic Engineering from Curtin University, a Certificate in Management Studies from the Singapore Institute of Management and a Diploma in Electrical Engineering from Singapore Polytechnic.

## ITEM 1A. RISK FACTORS

We operate in a rapidly changing environment that involves numerous uncertainties and risks. The following risks and uncertainties may have a material and adverse effect on our business, financial condition or results of operations. You should consider these risks and uncertainties carefully, together with all of the other information included or incorporated by reference in this Form 10-K. If any of the risks or uncertainties we face were to occur, the trading price of our securities could decline, and you may lose all or part of your investment.

#### **Risks Related to our Business and Strategy**

#### We have incurred losses since inception, and we may continue to incur substantial losses for the foreseeable future.

We have a limited operating history and have incurred significant losses in each fiscal year since our inception, including net losses of \$22.5 million, \$16.9 million and \$19.1 million during 2011, 2010 and 2009, respectively. As of December 31, 2011, we had an accumulated deficit of \$221.8 million. These losses have resulted principally from costs incurred in our research and development programs and from our manufacturing costs and selling, general and administrative expenses. We may continue to incur substantial operating and net losses and negative cash flow from operations. We expect that our selling, general and administrative expenses will continue to increase due to the additional operational and reporting costs associated with being a public company. We anticipate that our business will generate operating losses until we successfully implement our commercial development strategy and generate significant additional revenue to support our level of operating expenses. Because of the numerous risks and uncertainties associated with our commercialization efforts and future product development, we are unable to predict when we will become profitable, and we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase our profitability.

#### If our products fail to achieve and sustain sufficient market acceptance, our revenue will be adversely affected.

Our success depends, in part, on our ability to develop and market products that are recognized and accepted as reliable, enabling and cost-effective. Most of our potential customers already use expensive research systems in their laboratories and may be reluctant to replace those systems. Market acceptance of our systems will depend on many factors, including our ability to convince potential customers that our systems are an attractive alternative to existing technologies. Compared to some competing technologies, our microfluidic technology is relatively new, and most potential customers have limited knowledge of, or experience with, our products. Prior to adopting our microfluidic systems, some potential customers may need to devote time and effort to testing and validating our systems. Any failure of our systems to meet these customer benchmarks could result in customers choosing to retain their existing systems or to purchase systems other than ours.

In addition, it is important that our systems be perceived as accurate and reliable by the scientific and medical research community as a whole. Historically, a significant part of our sales and marketing efforts has been directed at convincing industry leaders of the advantages of our systems and encouraging such leaders to publish or present the results of their evaluation of our system. If we are unable to continue to induce leading researchers to use our systems or if such researchers are unable to achieve and publish or present significant experimental results using our systems, acceptance and adoption of our systems will be slowed and our ability to increase our revenue would be adversely affected.

# Our financial results may vary significantly from quarter-to-quarter due to a number of factors, which may lead to volatility in our stock price.

Our quarterly revenue and results of operations have varied in the past and may continue to vary significantly from quarter-to-quarter. For example, in 2008, 2009 and 2010, we experienced higher sales in the fourth quarter than in the first quarter of the next fiscal year. In addition, revenue from sales of our instruments relative to sales of our consumables may fluctuate or deviate significantly from expectations. The variability in our quarterly results of operations, including revenue from sales of our instruments relative to our consumables, may lead to volatility in our stock price as research analysts and investors respond to these quarterly fluctuations. These fluctuations are due to numerous factors that are difficult to forecast, including: fluctuations in demand for our products; changes in customer budget cycles and capital spending; seasonal variations in customer operations; tendencies among some customers to defer purchase decisions to the end of the quarter; the large unit value of our systems; changes in our pricing and sales policies or the pricing and sales policies of our competitors; our ability to design, manufacture and deliver products to our customers in a timely and cost-effective manner; quality control or yield problems in our manufacturing operations; our ability to timely obtain adequate quantities of the components used in our products; new product introductions and enhancements by us and our competitors; unanticipated increases in costs or expenses; our complex, variable and, at times, lengthy sales cycle; and fluctuations in foreign currency exchange rates. The foregoing factors, as well as other factors, could materially and adversely affect our quarterly and annual results of operations. In addition, a significant amount of our operating expenses are relatively fixed due to our manufacturing, research and development, and sales and general administrative efforts. Any failure to adjust spending quickly enough to compensate for a revenue shortfall could magnify the adverse impact of such revenue shortfall on our results of operations. We expect that our sales will continue to fluctuate on a quarterly basis and that our financial results for some periods may be below those projected by securities analysts, which could significantly decrease the price of our common stock.

#### Our future success is dependent upon our ability to expand our customer base and introduce new applications.

Our customer base is primarily composed of academic institutions, diagnostic laboratories, and pharmaceutical, biotechnology and Ag-Bio companies that perform analyses for research and commercial purposes. Our success will depend, in part, upon our ability to increase our market share among these customers, attract additional customers outside of these markets and market new applications to existing and new customers as we develop such applications. Attracting new customers and introducing new applications requires substantial time and expense. For example, it may be difficult to identify, engage and market to customers who are unfamiliar with the current applications of our systems. Any failure to expand our existing customer base or launch new applications would adversely affect our ability to increase our revenue.

# The life science research and Ag-Bio markets are highly competitive and subject to rapid technological change, and we may not be able to successfully compete.

The markets for our products are characterized by rapidly changing technology, evolving industry standards, changes in customer needs, emerging competition, new product introductions and strong price competition. We compete with both established and development stage life science research and Ag-Bio companies that design,

manufacture and market instruments and consumables for gene expression analysis, single-cell analysis, genotyping, PCR, digital PCR, other nucleic acid detection and additional applications using well established laboratory techniques, as well as newer technologies such as bead encoded arrays, microfluidics, nanotechnology, high-throughput DNA sequencing, microdroplets and photolithographic arrays. Most of our current competitors have significantly greater name recognition, greater financial and human resources, broader product lines and product packages, larger sales forces, larger existing installed bases, larger intellectual property portfolios and greater experience and scale in research and development, manufacturing and marketing than we do. For example, companies such as Affymetrix, Inc., Agilent Technologies, Inc., Bio-Rad Laboratories, Inc., Illumina, Inc., Life Technologies Corporation, LGC Limited, Luminex Corporation, NanoString Technologies, Inc., PerkinElmer, Inc. (through its acquisition of Caliper Life Sciences, Inc.), RainDance Technologies, Inc., Roche Applied Science (a division of Roche Diagnostics Corporation), Sequenom, Inc. and WaferGen Bio-systems, Inc. have products that compete in certain segments of the market in which we sell our products. In addition, a number of other companies and academic groups are in the process of developing novel technologies for life science markets.

Competitors may be able to respond more quickly and effectively than we can to new or changing opportunities, technologies, standards or customer requirements. In light of these advantages, even if our technology is more effective than the product or service offerings of our competitors, current or potential customers might accept competitive products and services in lieu of purchasing our technology. We anticipate that we will face increased competition in the future as existing companies and competitors develop new or improved products and as new companies enter the market with new technologies.

Increased competition is likely to result in pricing pressures, which could reduce our profit margins and increase our sales and marketing expenses, any of which could cause harm to our business, operating results and financial condition. Our failure to compete effectively could materially and adversely affect our business, financial condition and results of operations.

# We have limited experience in marketing, selling and distributing our products, and if we are unable to expand our direct sales and marketing force or distribution capabilities to adequately address our customers needs, our business may be adversely affected.

We have limited experience in marketing, selling and distributing our products. Our BioMark and EP1 systems for genomic analysis were introduced for commercial sale in 2006 and 2008, respectively. Our Access Array system for sample preparation was introduced for commercial sale in 2009, our BioMark HD system for genomic analysis was introduced for commercial sale in 2011 and we recently began producing and selling assays for use with our chips. We may not be able to market, sell and distribute our products effectively enough to support our planned growth.

We sell our products primarily through our own sales force and through distributors in certain territories. Our future sales will depend in large part on our ability to develop and substantially expand our direct sales force and to increase the scope of our marketing efforts. Our products are technically complex and used for highly specialized applications. As a result, we believe it is necessary to develop a direct sales force that includes people with specific scientific backgrounds and expertise and a marketing group with technical sophistication. Competition for such employees is intense. We may not be able to attract and retain personnel or be able to build an efficient and effective sales and marketing force, which could negatively impact sales of our products and reduce our revenue and profitability.

In addition, we may continue to enlist one or more sales representatives and distributors to assist with sales, distribution and customer support globally or in certain regions of the world. If we do seek to enter into such arrangements, we may not be successful in attracting desirable sales representatives and distributors, or we may not be able to enter into such arrangements on favorable terms. If our sales and marketing efforts, or those of any

third-party sales representatives and distributors, are not successful, our technologies and products may not gain market acceptance, which would materially and adversely impact our business operations.

Our business depends on research and development spending levels of academic, clinical and governmental research institutions, and pharmaceutical, biotechnology and Ag-Bio companies, a reduction in which could limit our ability to sell our products and adversely affect our business.

We expect that our revenue in the foreseeable future will be derived primarily from sales of our microfluidic systems and chips to academic institutions, diagnostic laboratories, and pharmaceutical, biotechnology and Ag-Bio companies worldwide. Our success will depend upon their demand for and use of our products. Accordingly, the spending policies of these customers could have a significant effect on the demand for our technology. These policies may be based on a wide variety of factors, including the resources available to make purchases, the spending priorities among various types of equipment, policies regarding spending during recessionary periods and changes in the political climate. In addition, academic, governmental and other research institutions that fund research and development activities may be subject to stringent budgetary constraints that could result in spending reductions, reduced allocations or budget cutbacks, which could jeopardize the ability of these customers to purchase our products. Our operating results may fluctuate substantially due to reductions and delays in research and development expenditures by these customers. For example, reductions in capital and operating expenditures by these customers may result in lower than expected sales of our microfluidic systems and chips. These reductions and delays may result from factors that are not within our control, such as:

changes in economic conditions;

natural disasters;

changes in government programs that provide funding to research institutions and companies;

changes in the regulatory environment affecting life science and Ag-Bio companies engaged in research and commercial activities;

differences in budget cycles across various geographies and industries;

market-driven pressures on companies to consolidate operations and reduce costs;

mergers and acquisitions in the life science and Ag-Bio industries; and

other factors affecting research and development spending.

Any decrease in our customers budgets or expenditures, or in the size, scope or frequency of capital or operating expenditures, could materially and adversely affect our operations or financial condition.

#### Some of our programs are partially supported by government grants, which may be reduced, withdrawn, delayed or reclaimed.

We have received and may continue to receive government grants to fund our research and development programs. For example, with the support of a grant from CIRM, we have developed a prototype microfluidic cell culture system that enables researchers to independently control the conditions for multiple cell cultures, allowing sequential dosing of a variety of factors and then extraction of the cells for further analysis. CIRM has awarded us with an additional grant over three years to further advance research in this area and to deliver useable prototypes to a limited number of stem cell research laboratories. Funding by governments may be significantly reduced or eliminated in the future for a number of reasons. For example, legal, social and ethical concerns surrounding the use of genetic information and biological materials in certain

#### Table of Contents

### Edgar Filing: FLUIDIGM CORP - Form 10-K

applications, such as stem cell research, genetic engineering or modification of agricultural products, and testing for genetic predisposition for certain medical conditions, may adversely impact funding levels for government grants in these areas. In addition, we may not receive funds under existing or future grants because of budgeting constraints of the agency

administering the program. A restriction on the government funding available to us would reduce the resources that we would be able to devote to existing and future research and development efforts. Such a reduction could delay the introduction of new products, harm our competitive position and adversely affect our business.

# We may not be able to develop new products or enhance the capabilities of our existing microfluidic systems to keep pace with rapidly changing technology and customer requirements, which could have a material adverse effect on our business, revenue, financial condition and operating results.

Our success depends on our ability to develop new products and applications for our technology in existing and new markets, while improving the performance and cost-effectiveness of our systems. New technologies, techniques or products could emerge that might offer better combinations of price and performance than our current or future product lines and systems. Existing markets for our products, including gene expression analysis, genotyping, digital PCR and single-cell analysis, as well as potential markets for our products such as high-throughput DNA sequencing and molecular diagnostics applications, are characterized by rapid technological change and innovation. It is critical to our success for us to anticipate changes in technology and customer requirements and to successfully introduce new, enhanced and competitive technology to meet our customers and prospective customers needs on a timely and cost-effective basis. Developing and implementing new technologies will require us to incur substantial development costs and we may not have adequate resources available to be able to successfully introduce new applications of, or enhancements to, our systems. We cannot guarantee that we will be able to maintain technological advantages over emerging technologies in the future. While we typically plan improvements to our systems, we may not be able to successfully implement these improvements. If we fail to keep pace with emerging technologies, demand for our systems will not grow and may decline, and our business, revenue, financial condition and operating results could suffer materially. In addition, if we introduce enhanced systems but fail to manage product transitions effectively, customers may delay or forgo purchases of our systems and our operating results may be adversely affected by product obsolescence and excess inventory. Even if we successfully implement some or all of these planned improvements, we cannot guarantee that our current and potential customers will find our enhanced systems to be an attractive alternative to existing technologies, including our current products.

# Emerging market opportunities may not develop as quickly as we expect, limiting our ability to successfully market and sell our products.

The application of our technologies to molecular diagnostics, single-cell analysis, digital PCR and sample preparation for next generation DNA sequencing are emerging market opportunities. We believe these opportunities will take several years to develop or mature and we cannot be certain that these market opportunities will develop as we expect. For example, we plan to launch a new system in the second half of 2012, which applies our technology to, among other things, improve single-cell analytic workflow for expression analysis. The future growth of the single-cell analysis market and the success of our new system depends on many factors beyond our control, including recognition and acceptance by the scientific community and the growth, prevalence and costs of competing methods of genetic analysis. If the market for single-cell analysis, molecular diagnostics, digital PCR and sample preparation for next generation DNA sequencing do not develop as we expect, our business may be adversely affected. Additionally, our success in these emerging markets may depend to a large extent on our ability to successfully market and sell products using our technologies. If we are not able successfully market and sell our products or to achieve the revenue or margins we expect, our operating results may be harmed and we may not recover our product development and marketing expenditures.

### If our research and product development efforts do not result in commercially viable products within the timeline anticipated, if at all, our business and results of operations will be adversely affected.

Our business is dependent on the improvement of our existing products, our development of new products to serve existing markets and our development of new products to create new markets and applications that were previously not practical with existing systems. We intend to devote significant personnel and financial resources

to research and development activities designed to advance the capabilities of our microfluidic systems technology. We have developed design rules for the implementation of our technology that are frequently revised to reflect new insights we have gained about the technology. In addition, we have discovered that biological or chemical reactions sometimes behave differently when implemented on our systems rather than in a standard laboratory environment. Furthermore, many such reactions take place within the confines of single cells, which have also demonstrated unexpected behavior when grown and manipulated within microfluidic environments. As a result, research and development efforts may be required to transfer certain reactions and cell handling techniques to our systems. In the past, product development projects have been significantly delayed when we encountered unanticipated difficulties in implementing a process on our systems. We may have similar delays in the future, and we may not obtain any benefits from our research and development activities. Any delay or failure by us to develop new products or enhance existing products would have a substantial adverse effect on our business and results of operations.

If any of our strategic partners fail to perform their obligations, terminate their agreements with us or do not diligently pursue product development or commercialization efforts, or if our collaborations do not lead to commercial products or services, we may not realize any material revenue or other benefits from the strategic partnerships, the costs from such strategic partnerships may exceed our benefits. Additionally, we may be required to dedicate substantial time and resources to our collaborations and strategic partnerships, and if we do not have adequate resources to fulfill our obligations under the collaboration and partnership agreements, as well as to operating and growing our business, our business may be adversely impacted.

We have entered into and may continue to enter into strategic partnerships, including collaborations and alliances with other participants in the life science, Ag-Bio and molecular diagnostics industries. If any of our strategic partners were to change their business strategies or development priorities, or encounter research and development obstacles, they may no longer be willing or able to participate in such strategic partnerships which could have a material adverse effect on our business, financial condition and results of operations. In addition, we may not control the strategic partnerships in which we participate. We may also have certain obligations, including some limited funding obligations, with regard to our strategic partnerships, joint ventures and alliances. We may be required to relinquish important rights, including intellectual property rights, and control over the development of our product candidates, assume product or other liabilities associated with the use of our products in diagnostic and other applications, agree to restrictions on the use or applications of our products, or otherwise be subject to terms unfavorable to us.

In 2010, we entered into collaboration agreements with Novartis V&D under which our capabilities in digital PCR are being developed for potential in-vitro diagnostics applications, with an initial focus on the development of an NIPD test for fetal aneuploidies. These agreements provide Novartis V&D with an option to exclusively license our technology in the primary field of non-invasive testing for fetal aneuploidies and the secondary field of non-invasive testing of genetic abnormality, disease or condition in a fetus or in a pregnant woman (other than as tested in the primary field), RhD genotyping or carrier status in a pregnant woman and the genetic carrier status of a prospective mother and her male partner (the Novartis Option ). Under these agreements, except with Novartis V&D, we cannot, directly or in collaboration with a third party, use, develop or sell any products or services in the primary field or the secondary field, other than for research applications in the secondary field. The agreements may be terminated by Novartis V&D at any time. At Novartis V&D s option, these agreements can be extended to encompass further research, development and commercialization of our products in the primary and secondary fields described above, which could take several years or more to complete. The agreements provide that if a test is commercialized, we would supply the required systems and chips for performance of such test.

If Novartis V&D elects to exercise the Novartis Option and extend our collaboration to encompass further research, development and commercialization of our products, we will be required to dedicate substantial time and resources to the collaboration, which may adversely impact our business operations. For example, we would

be required to expend significant time and energy recruiting and hiring qualified employees, particularly senior scientists and engineers, to fulfill our obligations under the collaboration agreement. Additionally, in the event the research and development leads to commercialization of products, we may need to establish an additional manufacturing facility to manufacture the products. Furthermore, due to the nature of the research and intended uses for the potential products, we may be required to comply with certain FDA regulations. Under our agreement with Novartis V&D, we will be required to conform some of our manufacturing operations to the FDA s good manufacturing practice regulations for medical devices, known as the Quality System Regulation, or QSR. The QSR is a complex regulatory scheme that governs the methods and documentation covering the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of medical device products. These and other related matters will require management s attention and oversight and our personnel s time, diverting attention from normal daily operation of our business, which could harm our business. Additionally, if we are required to add to our existing manufacturing space in Singapore or move some or all of our manufacturing facilities to a new location, such a move will involve significant time and expense, and we cannot assure you that such a move would not delay or otherwise adversely affect our manufacturing activities.

Our agreements and efforts with Novartis V&D are in their early stages and are subject to numerous conditions, contingencies, development challenges, milestones, royalty and license fees, indemnification obligations, termination rights, change of control and default provisions and regulatory approvals. We are engaged in discussions with Novartis V&D regarding the terms of the next phase of our collaboration plan. There can be no assurance that the discussions will lead to continued collaboration, that the collaboration will lead to technology, products or services, that such technology, products or services will receive market acceptance, that we will realize any material revenue or other benefits from this collaboration or that the benefits will exceed our costs.

### If one or more of our manufacturing facilities become unavailable or inoperable, we will be unable to continue manufacturing our instruments, chips and/or assays and, as a result, our business will be harmed until we are able to secure a new facility.

We manufacture and assemble all of our instruments and chips for commercial sale at our facility in Singapore and our assays for commercial sale at our headquarters in South San Francisco, California. No other manufacturing or assembly facilities are currently available to us, particularly facilities of the size and scope required by our Singapore operations. Our facilities and the equipment we use to manufacture our instruments, chips and assays would be costly to replace and could require substantial lead time to repair or replace. Our facilities may be harmed or rendered inoperable by natural or man-made disasters, including earthquakes, flooding and power outages, which may render it difficult or impossible for us to perform our research, development and manufacturing for some period of time. The inability to perform our research, development and manufacturing activities in Singapore and/or South San Francisco, combined with our limited inventory of reserve raw materials and manufactured supplies, may result in the loss of customers or harm our reputation, and we may be unable to reestablish relationships with those customers in the future. Although we possess insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all.

The current leases for our manufacturing facility in Singapore and South San Francisco expire at various times through October 2014 and April 2015, respectively. If we are unable to secure new leases upon the expiration of our current leases or if either of our facilities becomes otherwise unavailable to us, and we are required to move our operations to a new manufacturing facility, we will incur significant expense in connection with the establishment of a new facility. A move would be administratively and logistically challenging and would delay and otherwise adversely affect our manufacturing activities and business operations. We cannot provide assurances that we will be able to secure new leases on our existing manufacturing facilities or a new manufacturing facility on acceptable terms, if at all.

Our future capital needs are uncertain and we may need to raise additional funds in the future, which may cause dilution to stockholders or may be upon terms that are not favorable to us.

We believe that our existing cash and cash equivalents will be sufficient to meet our anticipated cash requirements for at least the next 18 months. However, we may need to raise substantial additional capital to:

expand the commercialization of our products;

fund our operations;

further our research and development; and

acquire other businesses or assets and license technologies. Our future funding requirements will depend on many factors, including:

market acceptance of our products;

the cost of our research and development activities;

the cost of filing and prosecuting patent applications;

the cost of defending, in litigation or otherwise, any claims that we infringe third-party patents or violate other intellectual property rights;

the cost and timing of regulatory clearances or approvals, if any;

the cost and timing of establishing additional sales, marketing and distribution capabilities;

the cost and timing of establishing additional technical support capabilities;

the effect of competing technological and market developments; and

the extent to which we acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

We cannot assure you that we will be able to obtain additional funds on acceptable terms, or at all. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any debt or additional equity financing that we raise may contain terms that are not favorable to us or our stockholders.

### Edgar Filing: FLUIDIGM CORP - Form 10-K

If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us. If we are unable to raise adequate funds, we may have to liquidate some or all of our assets, delay development or commercialization of our products or license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize. We also may have to reduce marketing, customer support or other resources devoted to our products or cease operations. Any of these factors could harm our operating results.

# To use our products, and our BioMark system in particular, customers typically need to purchase specialized reagents. Any interruption in the availability of these reagents for use in our products could limit our ability to market our products.

Our products, and our BioMark system in particular, must be used in conjunction with one or more reagents designed to produce or facilitate the particular biological or chemical reaction desired by the user. Many of these reagents are highly specialized and available to the user only from a single supplier or a limited number of suppliers. Although we sell reagents for use with certain of our products, our customers may purchase these reagents directly from third-party suppliers, and we have no control over the supply of those materials. In addition, our products are designed to work with these reagents as they are currently formulated. We have no control over the formulation of reagents sold by third-party suppliers, and the performance of our products might

be adversely affected if the formulation of these reagents is changed. If one or more of these reagents were to become unavailable or were reformulated, our ability to market and sell our products could be materially and adversely affected.

In addition, the use of a reagent for a particular process may be covered by one or more patents relating to the reagent itself, the use of the reagent for the particular process, the performance of that process or the equipment required to perform the process. Typically, reagent suppliers, who are either the patent holders or their authorized licensees, sell the reagents along with a license or covenant not to sue with respect to such patents. The license accompanying the sale of a reagent often purports to restrict the purposes for which the reagent may be used. If a patent holder or authorized licensee were to assert against us or our customers that the license or covenant relating to a reagent precluded its use with our systems, our ability to sell and market our products could be materially and adversely affected. For example, our BioMark system, which represented 36% of our product revenue in 2011 and 42% of our product revenue in 2010, involves real-time qPCR. Leading suppliers of reagents for real-time qPCR reactions include Life Technologies Corporation and Roche Applied Science, who are our direct competitors, and their licensees. These real-time qPCR reagents are typically sold pursuant to limited licenses or covenants not to sue with respect to patents held by these companies. We do not have any contractual supply agreements for these real-time qPCR reagents, and we cannot assure you that these reagents will continue to be available to our customers for use with our systems, or that these patent holders will not seek to enforce their patents against us, our customers, or suppliers.

### We are dependent on single source suppliers for some of the components and materials used in our products, and the loss of any of these suppliers could harm our business.

We rely on single source suppliers for certain components and materials used in our products. We do not have long term contracts with our suppliers of these components and materials. The loss of the single source suppliers of any of the following components and/or materials would require significant time and effort to locate and qualify an alternative source of supply:

The chips used in our microfluidic systems are fabricated using a specialized polymer that is available from a limited number of sources. In the past, we have encountered quality issues that have reduced our manufacturing yield or required the use of additional manufacturing processes.

The reader for our BioMark system requires specialized custom camera lenses, fiber light guides and other components that are available from a limited number of sources.

The raw materials for our DELTAgene and SNPtype assays and Access Array Target-Specific primers. Our reliance on these suppliers also subjects us to other risks that could harm our business, including the following:

we may be subject to increased component costs;

we may not be able to obtain adequate supply in a timely manner or on commercially reasonable terms;

our suppliers may make errors in manufacturing components that could negatively affect the efficacy of our products or cause delays in shipment of our products; and

our suppliers may encounter financial hardships unrelated to our demand for components, which could inhibit their ability to fulfill our orders and meet our requirements.

We have in the past experienced quality control and supply problems with some of our suppliers, such as manufacturing errors, and may again experience problems in the future. We may not be able to quickly establish additional or replacement suppliers, particularly for our single source components. Any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from

### Edgar Filing: FLUIDIGM CORP - Form 10-K

alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders or switch to competitive products.

#### We may experience development or manufacturing problems or delays that could limit the growth of our revenue or increase our losses.

We may encounter unforeseen situations in the manufacturing and assembly of our products that would result in delays or shortfalls in our production. In addition, our production processes and assembly methods may have to change to accommodate any significant future expansion of our manufacturing capacity. If we are unable to keep up with demand for our products, our revenue could be impaired, market acceptance for our products could be adversely affected and our customers might instead purchase our competitors products. Our inability to successfully manufacture our products would have a material adverse effect on our operating results.

All of our instruments and chips for commercial sale are manufactured at our facility in Singapore. Production of the elastomeric block that is at the core of our chips is a complex process requiring advanced clean rooms, sophisticated equipment and strict adherence to procedures. Any contamination of the clean room, equipment malfunction or failure to strictly follow procedures can significantly reduce our yield in one or more batches. We have in the past experienced variations in yields due to such factors. A drop in yield can increase our cost to manufacture our chips or, in more severe cases, require us to halt the manufacture of our chips until the problem is resolved. Identifying and resolving the cause of a drop in yield can require substantial time and resources.

In addition, developing a chip for a new application may require developing a specific production process for that type of chip. While all of our chips are produced using the same basic processes, significant variations may be required to ensure adequate yield of any particular type of chip. Developing such a process can be very time consuming, and any unexpected difficulty in doing so can delay the introduction of a product.

# Our shipments of products to customers are subject to delays or cancellation due to work stoppages or slowdowns, piracy, damage to shipping facilities caused by weather or terrorism, and congestion due to inadequacy of shipping equipment and other causes.

Because all our instruments and chips for commercial sale are manufactured at our facility in Singapore, we rely on shipping providers to deliver those products to our customers. Labor disputes, tariff or World Trade Organization-related disputes, piracy, physical damage to shipping facilities or equipment caused by severe weather or terrorist incidents, congestion at shipping facilities, inadequate equipment to load, dock and offload our products, energy-related tie-ups or other factors, could disrupt or delay shipping of our products from Singapore or off-loading our products upon arrival at their destination. Such disruptions or delays may have an adverse effect on our financial condition and results of operations.

#### If we are unable to recruit and retain key executives, scientists and technical support personnel, we may be unable to achieve our goals.

Our performance is substantially dependent on the performance of our senior management, particularly Gajus V. Worthington, our President and Chief Executive Officer. Additionally, to expand our research and product development efforts, we need key scientists skilled in areas such as molecular and cellular biology, assay development and manufacturing. We also need highly trained technical support personnel with the necessary scientific background and ability to understand our systems at a technical level to effectively support potential new customers and the expanding needs of current customers. Competition for these people is intense. Because of the complex and technical nature of our system and the dynamic market in which we compete, any failure to attract and retain a sufficient number of qualified employees could materially harm our ability to develop and commercialize our technology.

The loss of the services of any member of our senior management or our scientific or technical support staff might significantly delay or prevent the development of our products or achievement of other business objectives by diverting management s attention to transition matters and identification of suitable replacements, if any, and

could have a material adverse effect on our business. In addition, our research and product development efforts could be delayed or curtailed if we are unable to attract, train and retain highly skilled employees, particularly, senior scientists and engineers. We do not maintain fixed term employment contracts or significant key man life insurance with any of our employees.

# Adverse conditions in the global economy and disruption of financial markets may significantly harm our revenue, profitability and results of operations.

The global credit and financial markets have been experiencing volatility and disruptions, including diminished liquidity and credit availability, increased concerns about inflation and deflation, and the downgrade of U.S. debt and exposure risks on other sovereign debts, decreased consumer confidence, lower economic growth, volatile energy costs, increased unemployment rates and uncertainty about economic stability. Volatility and disruption of financial markets could limit our customers ability to obtain adequate financing or credit to purchase and pay for our products in a timely manner or to maintain operations, which could result in a decrease in sales volume that could harm our results of operations. General concerns about the fundamental soundness of domestic and international economic recovery of sectors which do not include our customers may reduce the resources available for government grants and related funding for life science, Ag-Bio and molecular diagnostics research and development. Continuation or further deterioration of these financial and macroeconomic conditions could significantly harm our sales, profitability and results of operations.

#### If we are unable to manage our anticipated growth effectively, our business could be harmed.

The rapid growth of our business has placed a significant strain on our managerial, operational and financial resources and systems. To execute our anticipated growth successfully, we must continue to attract and retain qualified personnel and manage and train them effectively. We must also upgrade our internal business processes and capabilities to create the scalability that a growing business demands.

We believe our facilities located in Singapore and South San Francisco, California, are sufficient to meet our short-term manufacturing needs. The current leases for our facilities in Singapore expire at various times through October 2014 and our current lease for our facilities in South San Francisco, California expires April 2015. In order to meet long-term demand for our microfluidic systems, we believe that we will need to add to our existing manufacturing space in Singapore or move all of our manufacturing facilities to a new location in Singapore in 2014. Such a move will involve significant expense in connection with the establishment of new clean rooms, the movement and installation of key manufacturing equipment and modifications to our manufacturing process, and we cannot assure you that such a move would not delay or otherwise adversely affect our manufacturing activities. We cannot provide assurances that we will be able to secure a lease on a new manufacturing facility on acceptable terms, if at all.

Further, our anticipated growth will place additional strain on our suppliers and manufacturing facilities, resulting in an increased need for us to carefully monitor quality assurance. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our development and commercialization goals.

### Our products could become subject to regulation as medical devices by the U.S. Food and Drug Administration or other regulatory agencies in the future.

Our products are currently labeled and sold to academic institutions, life sciences laboratories, and pharmaceutical, biotechnology and Ag-Bio companies for research purposes only, and not as diagnostic tests or medical devices. As products labeled for research use only, and used by our customers for research purposes

only, they are not subject to regulation as medical devices by the FDA or comparable agencies of other countries. However, if we change the labeling of our products in the future to include indications for human diagnostic applications or medical uses, or we have knowledge that our customers are using our products for diagnostic purposes, our products or related applications could be subject to the FDA s pre- and post-market regulations for medical devices. For example, if we wish to label and market our products for use in performing clinical diagnostics, we would first need to obtain FDA premarket clearance or approval, unless otherwise exempt from clearance or approval requirements. Obtaining FDA clearance or approval can be expensive and uncertain, and generally takes several months to years to obtain, and may require detailed and comprehensive scientific and clinical data. Notwithstanding the expense, these efforts may never result in FDA approval or clearance. Even if we were to obtain regulatory approval or clearance, it may not be for the uses we believe are important or commercially attractive.

Further, the FDA may expand its jurisdiction over our products or the products of our customers, which could impose restrictions on our ability to market and sell our products. For example, our customers may elect to use our research use only labeled products in their own laboratory developed tests, or LDTs, for clinical diagnostic use. The FDA has historically exercised enforcement discretion in not enforcing the medical device regulations against LDTs. However, the FDA could assert jurisdiction over some or all LDTs, which may impact our customers uses of our products. A significant change in the way that the FDA regulates our products or the LDTs that our customers develop may require us to change our business model in order to maintain compliance with these laws. The FDA held a meeting in July 2010, during which it indicated that it intends to reconsider its policy of enforcement discretion and to begin drafting a new oversight framework for LDTs. Additionally, in June 2011 the FDA issued a draft guidance document intended to clarify the types of in vitro diagnostic products that are properly labeled for research use only. The draft guidance states that merely including a labeling statement that the product is for research purposes only will not necessarily render the device exempt from the FDA s clearance, approval, or other requirements if the circumstances surrounding the distribution of the product indicate that the manufacturer knows its product is, or intends for its product to be, offered for clinical diagnostic uses. These circumstances may include written or verbal marketing claims regarding a product s performance in clinical applications and a manufacturer s provision of technical support for clinical applications. If the FDA imposes significant changes to the regulation of LDTs, or modifies its approach to our products labeled for research use only, but which may be used by our customers for clinical use, it could reduce our revenue or increase our costs and adversely affect our business, prospe

We may be required to proactively achieve compliance with certain FDA regulations and to conform our manufacturing operations to the QSR as part of our contracts with customers or as part of our collaborations with third parties. In addition, we may voluntarily seek to conform our manufacturing operations to the QSR. For clinical diagnostic products that are regulated as medical devices, the FDA enforces the QSR through periodic unannounced inspections of registered manufacturing facilities. If we are required to comply with the QSR, the failure to take satisfactory corrective action in response to an adverse QSR inspection could result in enforcement actions, including a public warning letter, a shutdown of manufacturing operations, a product recall, civil or criminal penalties or other sanctions, which could in turn cause our sales and business to suffer.

# Our products could have unknown defects or errors, which may give rise to claims against us, adversely affect market adoption of our systems and adversely affect our business, financial condition and results of operations.

Our microfluidic systems utilize novel and complex technology applied on a nanoliter scale and such systems may develop or contain undetected defects or errors. We cannot assure you that material performance problems, defects or errors will not arise, and as we increase the density and integration of our microfluidic systems, these risks may increase. We generally provide warranties that our microfluidic systems will meet performance expectations and will be free from defects. We also provide warranties relating to other parts of our microfluidic systems. The costs incurred in correcting any defects or errors may be substantial and could adversely affect our operating margins.

In manufacturing our products, including our systems, chips and assays, we depend upon third parties for the supply of various components, many of which require a significant degree of technical expertise to produce. In addition, we purchase certain products from third-party suppliers for resale. If our suppliers fail to produce components to specification or provide defective products to us for resale and our quality control tests and procedures fail to detect such errors or defects, or if we or our suppliers use defective materials or workmanship in the manufacturing process, the reliability and performance of our products will be compromised.

If our products contain defects, we may experience:

a failure to achieve market acceptance or expansion of our product sales;

loss of customer orders and delay in order fulfillment;

damage to our brand reputation;

increased cost of our warranty program due to product repair or replacement;

product recalls or replacements;

inability to attract new customers;

diversion of resources from our manufacturing and research and development departments into our service department; and

legal claims against us, including product liability claims, which could be costly and time consuming to defend and result in substantial damages.

In addition, certain of our products are marketed for use with products sold by third parties. For example, our Access Array system is marketed as compatible with all major next generation DNA sequencing instruments. If such third-party products are not produced to specification, are produced in accordance with modified specifications or are defective, they may not be compatible with our products. In such case, the reliability and performance of our products may be compromised.

The occurrence of any one or more of the foregoing could negatively affect our business, financial condition and results of operations.

### We generate a substantial portion of our revenue internationally and are subject to various risks relating to such international activities which could adversely affect our international sales and operating performance.

During 2011, 2010 and 2009, approximately 47%, 46% and 48%, respectively, of our product revenue was generated from sales to customers located outside of the United States. We believe that a significant percentage of our future revenue will come from international sources as we expand our overseas operations and develop opportunities in other international areas. In addition, all of our instruments and chips for commercial sale are manufactured in Singapore. Our international business may be adversely affected by changing economic, political and regulatory conditions in foreign countries.

Because the majority of our product sales are currently denominated in U.S. dollars, if the value of the U.S. dollar increases relative to foreign currencies, our products could become more costly to the international consumer and therefore less competitive in international markets, which could affect our financial performance. If the value of the U.S. dollar decreases relative to the Singapore dollar, it would become more costly in U.S. dollars for us to manufacture our products in Singapore, which would adversely affect our revenue and product margins. Furthermore, fluctuations in exchange rates could reduce our revenue and affect demand for our products.

### Table of Contents

Engaging in international business inherently involves a number of other difficulties and risks, including:

required compliance with existing and changing foreign regulatory requirements and laws;

required compliance with anti-bribery laws, such as the U.S. Foreign Corrupt Practices Act and U.K. Bribery Act, data privacy requirements, labor laws and anti-competition regulations;

export or import restrictions;

laws and business practices favoring local companies;

longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;

political and economic instability;

potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and other trade barriers;

difficulties and costs of staffing and managing foreign operations; and

difficulties protecting or procuring intellectual property rights. If one or more of these risks occurs, it could require us to dedicate significant resources to remedy, and if we are unsuccessful in finding a solution, our financial results will suffer.

#### If we are unable to integrate future acquisitions successfully, our operating results and prospects could be harmed.

In the future, we may make acquisitions to improve our product offerings or expand into new markets. Our future acquisition strategy will depend on our ability to identify, negotiate, complete and integrate acquisitions and, if necessary, to obtain satisfactory debt or equity financing to fund those acquisitions. Mergers and acquisitions are inherently risky, and any transaction we complete may not be successful. Any merger or acquisition we may pursue would involve numerous risks, including the following:

difficulties in integrating and managing the operations, technologies and products of the companies we acquire;

diversion of our management s attention from normal daily operation of our business;

our inability to maintain the key business relationships and the reputations of the businesses we acquire;

our inability to retain key personnel of the acquired company;

### Edgar Filing: FLUIDIGM CORP - Form 10-K

uncertainty of entry into markets in which we have limited or no prior experience and in which competitors have stronger market positions;

our dependence on unfamiliar affiliates and customers of the companies we acquire;

insufficient revenue to offset our increased expenses associated with acquisitions;

our responsibility for the liabilities of the businesses we acquire, including those which we may not anticipate; and

our inability to maintain internal standards, controls, procedures and policies.

We may be unable to secure the equity or debt funding necessary to finance future acquisitions on terms that are acceptable to us. If we finance acquisitions by issuing equity or convertible debt securities, our existing stockholders will likely experience dilution, and if we finance future acquisitions with debt funding, we will incur interest expense and may have to comply with financial covenants and secure that debt obligation with our assets.

## If we fail to maintain effective internal control over financial reporting in the future, the accuracy and timing of our financial reporting may be impaired, which could adversely affect our business and our stock price.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Our testing may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses. Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management time on compliance-related issues. We currently do not have an internal audit group and we will evaluate the need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. Moreover, if we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would require additional financial and management resources.

# Risks associated with a company-wide implementation of an enterprise resource planning, or ERP, system may adversely affect our business and results of operations or the effectiveness of internal control over financial reporting.

We have been implementing a company-wide ERP system to handle the business and financial processes within our operations and corporate functions. ERP implementations are complex and time-consuming projects that involve substantial expenditures on system software and implementation activities that can continue for several years. ERP implementations also require transformation of business and financial processes in order to reap the benefits of the ERP system. Our business and results of operations may be adversely affected if we experience operating problems and/or cost overruns during the ERP implementation process, or if the ERP system and the associated process changes do not give rise to the benefits that we expect. Additionally, if we do not effectively implement the ERP system as planned or if the system does not operate as intended, it could adversely affect the effectiveness of our internal controls over financial reporting.

#### Our ability to use net operating losses to offset future taxable income may be subject to certain limitations.

In general, under Section 382 of the Internal Revenue Code, a corporation that undergoes an ownership change is subject to limitations on its ability to utilize its pre-change net operating losses, or NOLs, to offset future taxable income. If we undergo ownership changes, our ability to utilize NOLs could be limited by Section 382 of the Internal Revenue Code. Future changes in our stock ownership, some of which are outside of our control, could result in an ownership change under Section 382 of the Internal Revenue Code. Because we may not be able to utilize a material portion of the NOLs reflected on our balance sheet, we have fully reserved against the value of our NOLs on our balance sheet.

#### **Risks Related to Intellectual Property**

#### Our ability to protect our intellectual property and proprietary technology through patents and other means is uncertain.

Our commercial success depends in part on our ability to protect our intellectual property and proprietary technologies. We rely on patent protection, where appropriate and available, as well as a combination of copyright, trade secret and trademark laws, and nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Our pending U.S. and

foreign patent applications may not issue as patents or may not issue in a form that will be sufficient to protect our proprietary technology and gain or keep our competitive advantage. Any patents we have obtained or do obtain may be subject to re-examination, reissue, opposition or other administrative proceeding, or may be challenged in litigation, and such challenges could result in a determination that the patent is invalid or unenforceable. In addition, competitors may be able to design alternative methods or devices that avoid infringement of our patents. Both the patent application process and the process of managing patent disputes can be time consuming and expensive.

Furthermore, the laws of some foreign countries may not protect our intellectual property rights to the same extent as do the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Changes in either the patent laws or in interpretations of patent laws in the United States or other countries may diminish the value of our intellectual property. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. For example:

We might not have been the first to make the inventions covered by each of our pending patent applications;

We might not have been the first to file patent applications for these inventions;

Others may independently develop similar or alternative products and technologies or duplicate any of our products and technologies;

It is possible that none of our pending patent applications will result in issued patents, and even if they issue as patents, they may not provide a basis for commercially viable products, or may not provide us with any competitive advantages, or may be challenged and invalidated by third parties;

We may not develop additional proprietary products and technologies that are patentable;

The patents of others may have an adverse effect on our business; and

We apply for patents covering our products and technologies and uses thereof, as we deem appropriate. However, we may fail to apply for patents on important products and technologies in a timely fashion or at all.

To the extent our intellectual property, including licensed intellectual property, offers inadequate protection, or is found to be invalid or unenforceable, our competitive position and our business could be adversely affected.

#### We may be involved in lawsuits to protect or enforce our patents and proprietary rights, to determine the scope, coverage and validity of others proprietary rights, or to defend against third party claims of intellectual property infringement, any of which could be time-intensive and costly and may adversely impact our business or stock price.

Litigation may be necessary for us to enforce our patent and proprietary rights and/or to determine the scope, coverage and validity of others proprietary rights. Litigation could result in substantial legal fees and could adversely affect the scope of our patent protection. The outcome of any litigation or other proceeding is inherently uncertain and might not be favorable to us, and we might not be able to obtain licenses to technology that we require. Even if such licenses are obtainable, they may not be available at a reasonable cost. We could therefore incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our gross margins. Further, we could encounter delays in product introductions, or interruptions in product sales, as we develop alternative methods or products.

As we move into new markets and applications for our products, incumbent participants in such markets may assert their patents and other proprietary rights against us as a means of slowing our entry into such markets

or as a means to extract substantial license and royalty payments from us. Our commercial success may depend in part on our non-infringement of the patents or proprietary rights of third parties. Numerous significant intellectual property issues have been litigated, and will likely continue to be litigated, between existing and new participants in our existing and targeted markets and competitors may assert that our products infringe their intellectual property rights as part of a business strategy to impede our successful entry into those markets. Third parties may assert that we are employing their proprietary technology without authorization. For example, on June 4, 2008 we received a letter from Applied Biosystems, Inc., now Life Technologies Corporation, asserting that our BioMark system for gene expression analysis infringes upon U.S. Patent No. 6,814,934, or the 934 patent, and its foreign counterparts in Europe and Canada. In June 2011, we resolved this dispute by entering into a license agreement with Life Technologies Corporation which, among other matters, granted us a non-exclusive license to the 934 patent and its foreign counterparts.

In addition, our agreements with some of our suppliers, distributors, customers and other entities with whom we do business may require us to defend or indemnify these parties to the extent they become involved in infringement claims against us, including the claims described above. We could also voluntarily agree to defend or indemnify third parties in instances where we are not obligated to do so if we determine it would be important to our business relationships. If we are required or agree to defend or indemnify any of these third parties in connection with any infringement claims, we could incur significant costs and expenses that could adversely affect our business, operating results, or financial condition.

#### We depend on certain technologies that are licensed to us. We do not control these technologies and any loss of our rights to them could prevent us from selling our products, which would have an adverse effect on our business.

We rely on licenses in order to be able to use various proprietary technologies that are material to our business, including our core integrated fluidic circuit and multi-layer soft lithography technologies. Our rights to use the technology we license are subject to the negotiation of, continuation of and compliance with the terms of those licenses. In some cases, we do not control the prosecution, maintenance, or filing of the patents to which we hold licenses, or the enforcement of these patents against third parties.

Certain of our licenses contain provisions that allow the licensor to terminate the license upon specific conditions. Our rights under the licenses are subject to our continued compliance with the terms of the license, including the payment of royalties due under the license. Termination of these licenses could prevent us from marketing some or all of our products. Because of the complexity of our products and the patents we have licensed, determining the scope of the license and related royalty obligation can be difficult and can lead to disputes between us and the licensor. An unfavorable resolution of such a dispute could lead to an increase in the royalties payable pursuant to the license. If a licensor believed we were not paying the royalties due under the license or were otherwise not in compliance with the terms of the license, the licensor might attempt to revoke the license. If such an attempt were successful, we might be barred from producing and selling some or all of our products.

# We are subject to certain manufacturing restrictions related to licensed technologies that were developed with the financial assistance of U.S. governmental grants.

We are subject to certain U.S. government regulations because we have licensed technologies that were developed with U.S. government grants. In accordance with these regulations, these licenses provide that products embodying the technologies are subject to domestic manufacturing requirements. If this domestic manufacturing requirement is not met, the government agency that funded the relevant grant is entitled to exercise specified rights, referred to as march-in rights , which if exercised would allow the government agency to require the licensors or us to grant a non-exclusive, partially exclusive or exclusive license in any field of use to a third party designated by such agency. All of our microfluidic systems revenue is dependent upon the availability of our chips, which incorporate technology developed with U.S. government grants. All of our

instruments, including microfluidic systems, and chips for commercial sale are manufactured at our facility in Singapore. The federal regulations allow the funding government agency to grant, at the request of the licensors of such technology, a waiver of the domestic manufacturing requirement. Waivers may be requested prior to any government notification. We have assisted the licensors of these technologies with the analysis of the domestic manufacturing requirement, and, in December 2008, one of the licensors applied for a waiver of the domestic manufacturing requirement with respect to certain patents. In July 2009, the funding government agency granted the requested waiver of the domestic manufacturing requirement for a three year period commencing in July 2009. If in the future it were to be determined that we are in violation of the domestic manufacturing requirement and additional waivers of such requirement were either not requested or not granted, then the U.S. government could exercise its march-in rights. In addition, these licenses contain provisions relating to compliance with this domestic manufacturing requirement. If it were determined that we are not in compliance with these provisions and such non-compliance constituted a material breach of the licenses, the licenses could be terminated. Either the exercise of march-in rights or the termination of one or more of our licenses could materially adversely affect our business, operations and financial condition.

### We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our employees former employers.

Many of our employees were previously employed at universities or other life science or Ag-Bio companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. A loss of key research personnel work product could hamper or prevent our ability to commercialize certain potential products, which could severely harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

#### **Risks Related to Our Common Stock**

#### We expect that our stock price will fluctuate significantly, and holders may have difficulty selling their shares.

Our stock is currently traded on NASDAQ, but we can provide no assurance that there will be active trading on that market or any other market in the future. If there is no active trading market or if the volume of trading is limited, holders of our common stock may have difficulty selling their shares. In addition, the trading price of our common stock may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include:

actual or anticipated quarterly variation in our results of operations or the results of our competitors;

announcements or communications by us or our competitors relating to, among other things, new commercial products, technological advances, significant contracts, commercial relationships, capital commitments, acquisitions or sales of businesses and/or misperceptions in or speculation by the market regarding such announcements or communications;

issuance of new or changed securities analysts reports or recommendations for our stock;

developments or disputes concerning our intellectual property or other proprietary rights;

commencement of, or our involvement in, litigation;

market conditions in the life science, Ag-Bio and molecular diagnostics sectors;

### Edgar Filing: FLUIDIGM CORP - Form 10-K

failure to complete significant sales;

manufacturing disruptions that could occur if we were unable to successfully expand our production in our current or an alternative facility;

any future sales of our common stock or other securities in connection with raising additional capital or otherwise;

any major change to the composition of our board of directors or management; and

general economic conditions and slow or negative growth of our markets.

The stock market in general, and market prices for the securities of technology-based companies like ours in particular, have from time to time experienced volatility that often has been unrelated to the operating performance of the underlying companies. These broad market and industry fluctuations may adversely affect the market price of our common stock, regardless of our operating performance. In several recent situations where the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit against us, the defense and disposition of the lawsuit could be costly and divert the time and attention of our management and harm our operating results.

### If securities or industry analysts publish unfavorable research about our business or cease to cover our business, our stock price and trading volume could decline.

The trading market for our common stock may rely, in part, on the research and reports that equity research analysts publish about us and our business. We do not have any control of the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

#### Future sales of shares could cause our stock price to decline.

If stockholders holding shares of our common stock sell, or indicate an intention to sell, substantial amounts of their common stock in the public market, the trading price of our common stock could decline. As of December 31, 2011, we had outstanding a total of 20,321,434 shares of common stock, 11,150,774 of which were freely tradable, without restriction, in the public market. In addition, 1,598,606 shares of common stock that are issuable upon exercise of vested options as of December 31, 2011 will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements and Rules 144 and 701 under the Securities Act. If a substantial amount of our shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

### Our directors and executive officers will continue to have substantial control over and could limit your ability to influence the outcome of key transactions, including changes of control.

As of December 31, 2011, our current executive officers, directors and their affiliates beneficially owned or controlled approximately 7.5% of the outstanding shares of our common stock. Accordingly, these executive officers, directors and their affiliates, acting as a group, can have substantial influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transactions. These stockholders may also delay or prevent a change of control of us, even if such a change of control would benefit our other stockholders. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors perception that conflicts of interest may exist or arise.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management and limit the market price of our common stock.

Provisions in our certificate of incorporation and bylaws may have the effect of delaying or preventing a change of control or changes in our management, including provisions that:

authorize our board of directors to issue, without further action by the stockholders, up to 10,000,000 shares of undesignated preferred stock;

require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;

specify that special meetings of our stockholders can be called only by our board of directors, the Chairman of the board, the Chief Executive Officer or the President;

establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;

establish that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered three year terms;

provide that our directors may be removed only for cause;

provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;

specify that no stockholder is permitted to cumulate votes at any election of directors; and

require a super-majority of votes to amend certain of the above-mentioned provisions.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us.

#### We have never paid dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future.

We have paid no cash dividends on any of our classes of capital stock to date, have contractual restrictions against paying cash dividends and currently intend to retain our future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be stockholders sole source of gain for the foreseeable future.

### Edgar Filing: FLUIDIGM CORP - Form 10-K

ITEM 1B. UNRESOLVED STAFF COMMENTS None.

#### ITEM 2. PROPERTIES

We lease approximately 30,000 square feet of office and laboratory space at our headquarters in South San Francisco, California under a lease that expires in April 2015, approximately 28,000 square feet of manufacturing and office space at our facility in Singapore under leases with varying expiration dates through October 2014. In addition, we lease office space in Paris, France on a month-to-month basis; in Tokyo, Japan under a lease that expires in November 2013; in Osaka, Japan under a lease that expires in September 2012; and in Shanghai, China under a lease that expires in May 2013. We believe that our existing office, laboratory and manufacturing space, together with additional space and facilities available on commercially reasonable terms, will be sufficient to meet our needs through 2013. In addition, we believe that our properties are in good condition and are adequate and suitable for their purposes.

#### ITEM 3. LEGAL PROCEEDINGS

We are not currently engaged in any material legal proceedings.

#### ITEM 4. MINE SAFETY DISCLOSURE

Not applicable.

#### PART II

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

#### Market for Our Common Stock; Dividends

Our common stock began trading on the NASDAQ Global Market under the symbol FLDM on February 10, 2011. The following table sets forth the range of high and low sales prices of our common stock for the periods indicated:

Year ended December 31, 2011	High	Low
February 10, 2011 through March 31, 2011	\$ 16.97	\$13.13
Second Quarter	\$ 18.24	\$13.50
Third Quarter	\$ 20.20	\$ 11.64
Fourth Quarter	\$ 15.00	\$ 12.05

We had approximately 173 stockholders of record as of February 29, 2012; however, because many of our outstanding shares are held in accounts with brokers and other institutions, we believe we have more beneficial owners. We have never declared or paid dividends on our common stock and do not expect to pay dividends on our common stock for the foreseeable future. Instead, we anticipate that all of our earnings in the foreseeable future will be used for the operation and growth of our business.

#### Stock Performance Graph

The following performance graph shall not be deemed soliciting material or to be filed with the Securities and Exchange Commission for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any filing of Fluidigm Corporation under the Securities Act or the Exchange Act.

The following graph shows a comparison from February 10, 2011 (the date our common stock commenced trading on the NASDAQ Global Market) through December 31, 2011 of cumulative total return for our common stock, the NASDAQ Composite Index and the NASDAQ Biotechnology Index. Such returns are based on historical results and are not intended to suggest future performance. Data for the NASDAQ Composite Index and the NASDAQ Biotechnology Index assume reinvestment of dividends.

#### Sales of Unregistered Securities

None.

#### Use of Proceeds

Through December 31, 2011, the net proceeds from the initial public offering of our common stock, or IPO, have been applied as follows: \$5.0 million for the repayment of promissory notes issued in January 2011, \$3.1 million for the repayment of our bank line of credit, \$12.3 million for research and development expenses, \$9.3 million for general corporate purposes including selling, general and administrative expenses and litigation settlement expense, and \$1.7 million for capital expenditures. On June 30, 2011, we paid \$3.0 million in connection with the settlement of certain patent litigation with Life. In July 2011, we paid Life an additional \$2.0 million in connection with our exercise of an option under the terms of our agreements with Life to limit or preclude certain patent litigation between the parties over a period of two to four years. Other than the aggregate payment of \$5.0 million to Life, there has been no material change in the planned use of proceeds from our IPO from that described in the final prospectus filed with the SEC pursuant to Rule 424(b) on February 10, 2011.

#### ITEM 6. SELECTED FINANCIAL DATA

The following selected financial data should be read in conjunction with the consolidated financial statements and related notes thereto appearing elsewhere in this Form 10-K. We have derived the consolidated statement of operations data for the years ended December 31, 2011, 2010 and 2009 and consolidated balance sheet data as of December 31, 2011 and 2010 from audited consolidated financial statements included elsewhere in this Form 10-K. The consolidated statement of operations data for the fiscal years ended December 27, 2008 and December 29, 2007 and the consolidated balance sheet data as of December 31, 2009, December 27, 2008 and December 29, 2007 were derived from audited consolidated financial statements that are not included in this Form 10-K.

	Year Ended							
	December 31, 2011	December 31, 2010	December 31, 2009	December 27, 2008	December 29, 2007			
	(in thousands, except per share amounts)							
Consolidated Statement of Operations Data:								
Total revenue	\$ 42,865	\$ 33,560	\$ 25,412	\$ 15,347	\$ 7,275			
Loss from operations	(18,566)	(14,573)	(18,037)	(29,543)	(23,526)			
Net loss attributed to common stockholders	(32,370)	(16,902)	(19,128)	(29,499)	(25,451)			
Net loss per share attributed to common								
stockholders, basic and diluted	(1.81)	(8.94)	(11.02)	(17.85)	(15.93)			
Consolidated Balance Sheet Data:								
Cash, cash equivalents and short and long-term								
investments	\$ 54,967	\$ 5,723	\$ 14,602	\$ 17,796	\$ 40,363			
Working capital	49,862	2,369	21,354	20,704	38,754			
Total assets	79,326	24,801	32,153	32,354	54,776			
Total long-term debt	10,138	14,700	14,461	15,212	9,362			
Convertible promissory notes					4,997			
Convertible preferred stock		184,550	183,845	167,538	162,082			
Total stockholders' equity (deficit)	56,897	(189,167)	(173,619)	(158,339)	(130,331)			

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

The following discussion and analysis should be read together with our consolidated financial statements and the notes to those statements included elsewhere in this Form 10-K. This discussion contains forward-looking statements based on our current expectations, assumptions, estimates and projections about Fluidigm and our industry. These forward-looking statements involve risks and uncertainties. Our actual results could differ materially from those indicated in these forward-looking statements as a result of certain factors, as more fully described in Risk factors in Item IA of this Form 10-K, in this Item 7, and elsewhere in this Form 10-K. We undertake no obligation to update publicly any forward-looking statements for any reason, even if new information becomes available or other events occur in the future.

#### Overview

We develop, manufacture and market microfluidic systems for growth markets in the life science and agricultural biotechnology, or Ag-Bio, industries. Our proprietary microfluidic systems consist of instruments and consumables, including chips, assays and other reagents. Our systems are designed to significantly simplify experimental workflow, increase throughput and reduce costs, while providing the excellent data quality demanded by our customers. In addition, our proprietary technology enables genetic analysis that in many instances was previously impractical. We actively market three microfluidic systems, including eight different commercial chips for nucleic acid research and three families of assays, to leading academic institutions, diagnostic laboratories, and pharmaceutical, biotechnology and Ag-Bio companies. We have sold over 500 systems to customers in over 25 countries worldwide.

We have launched several product lines, including our BioMark system for gene expression analysis, genotyping and digital PCR in 2006, our EP1 system for SNP genotyping and digital PCR in 2008, our Access Array system for target enrichment in 2009, and our BioMark HD real-time PCR system for high throughput gene expression analysis, single-cell analysis, SNP genotyping and digital PCR in 2011. In 2011, we also launched our assay and reagent products, including our DELTAgene assays for gene expression, including single-cell analysis, our SNPtype assays for SNP genotyping, and our Access Array Target-Specific primers for next generation DNA sequencing. Our systems utilize one or more chips designed for particular applications and include specialized instrumentation and software, as well as assays and other reagents for certain applications.

We distribute our microfluidic systems through our direct sales force and support organizations located in North America, Europe and Asia-Pacific, and through distributors or sales agents in several European, Latin American, Middle Eastern and Asia-Pacific countries. Our manufacturing operations are primarily located in Singapore. Our facility in Singapore manufactures our instruments and fabricates all of our chips for commercial sale and for our research and development purposes. Our South San Francisco facility fabricates chips for our own research and development purposes and manufactures our assays and produces other reagents for commercial sale.

Since 2002, we have received revenue from government grants. Our most significant grant relationship has been with the Singapore Economic Development Board, or EDB. The EDB, an agency of the Government of Singapore, promotes research, development and manufacturing activities in Singapore and associated employment of Singapore nationals by providing incentive grants to companies conducting operations in Singapore that satisfy the requirements of EDB s government programs. Under our agreements with EDB, we were eligible to receive incentive grant payments from EDB, provided we satisfied certain agreed upon targets. Our agreements with EDB provided for incentive funding eligibility through May 2011. From January 1, 2009 through December 31, 2011, we recognized \$2.7 million of grant revenue from EDB.

Our total revenue grew from \$25.4 million in 2009 to \$42.9 million in 2011. We have incurred significant net losses since our inception in 1999 and, as of December 31, 2011, our accumulated deficit was \$221.8 million.

#### **Critical Accounting Policies, Significant Judgments and Estimates**

Our consolidated financial statements and the related notes included elsewhere in this Form 10-K are prepared in accordance with accounting principles generally accepted in the United States. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, costs and expenses and related disclosures. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Changes in accounting estimates may occur from period to period. Accordingly, actual results could differ significantly from the estimates made by our management. We evaluate our estimates and assumptions on an ongoing basis. To the extent that there are material differences between these estimates and actual results, our future financial statement presentation, financial condition, results of operations and cash flows will be affected.

We believe that the following critical accounting policies involve a greater degree of judgment and complexity than our other accounting policies. Accordingly, these are the policies we believe are the most critical to understanding and evaluating our consolidated financial condition and results of operations. Our accounting policies are more fully described in Note 2 of the notes to our audited consolidated financial statements.

#### **Revenue Recognition**

We generate revenue from sales of our products, license and collaboration arrangements, research and development contracts and government grants. Our products consist of instruments and consumables, including chips, assays and other reagents related to our microfluidic systems. Product revenue includes services for instrument installation, training and customer support. We do not sell software separately; however, we offer post-contract software support services for certain of our instruments that contain software that is essential to their functionality. We have entered into collaboration, license, and research and development contracts, and have received government grants to conduct research and development activities.

Revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price to the buyer is fixed or determinable, and collectibility is reasonably assured. Revenue from the sales of our products that are not part of multiple element arrangements are recognized when no significant obligation remains undelivered and collection is reasonably assured, which is generally when delivery has occurred. Delivery occurs when there is a transfer of title and risk of loss passes to the buyer. Payments received in advance of revenue recognition are classified as deferred revenue in the consolidated balance sheets.

The evaluation of these revenue recognition criteria requires significant management judgment. For instance, we use judgment to assess collectibility based on factors such as the customer s creditworthiness and past collection history, if applicable. If we determine that collection is not reasonably assured, revenue recognition is deferred until receipt of payment. We also use judgment to assess whether a price is fixed or determinable, including, but not limited to, reviewing contractual terms and conditions related to payment.

Certain of our sales contracts involve the delivery or performance of multiple products or services. Significant contract interpretation is sometimes required to determine the appropriate accounting for revenue from multiple element arrangements, including whether the deliverables should be treated as separate units of accounting for revenue recognition purposes, how the related sales price should be allocated among the elements, when to recognize revenue for each element and the period over which revenue should be recognized. Revenue recognition for contracts with multiple deliverables is based on the individual units of accounting determined to exist in the contract.

On January 1, 2011, new accounting guidance regarding revenue recognition for arrangements with multiple deliverables became effective. As a result, for sales of products and services after 2010, we allocate the contract consideration at the inception of the contract to the deliverables based upon their relative selling prices. A

delivered item is considered to be a separate unit of accounting when it has value to the customer on a stand-alone basis. We use our best estimate of selling price for individual deliverables when vendor specific objective evidence or third-party evidence is unavailable. When the contractual price of each deliverable in an arrangement falls within the range established for estimated selling prices, we recognize revenue for the deliverable based on the contractual price. In other cases, we allocate revenue to each deliverable based on its selling price. Revenue is only recognized for each deliverable when the revenue recognition criteria have been met.

For sales of products and services prior to 2011, we allocated revenue for transactions that included multiple elements to each unit of accounting based on its relative fair value, and recognized revenue for each unit of accounting when the applicable revenue recognition criteria were met. When objective and reliable evidence of fair value existed for the undelivered items but not for the delivered items, the residual method was used to allocate arrangement consideration. Under the residual method, the amount of arrangement consideration allocated to the delivered items equaled the total arrangement consideration less the aggregate fair value of the undelivered items. When we were unable to establish stand-alone value for delivered items or when fair value of undelivered items had not been established, revenue was deferred until all elements were delivered and services had been performed, or until fair value could objectively be determined for any remaining undelivered elements. If the only undelivered element was post-contract software support services for which objective and reliable evidence of fair value had not been established, the entire arrangement consideration was recognized ratably over the service period.

Until the third quarter of 2009, product installation was considered essential to the functionality of our BioMark systems. Accordingly, revenue recognition for all sales of our BioMark systems began upon installation. During the third quarter of 2009, we began shipping our BioMark systems fully-assembled and calibrated. We concluded that installation was no longer essential to the functionality of these instruments since the installation could be performed by the customer or an independent third party. As a result, beginning in the fourth quarter of 2009, we have treated our BioMark systems and their related installation as separate units of accounting and instrument revenue is recognized upon delivery, provided that other applicable revenue recognition criteria have been satisfied. Installation revenue is recognized when the installation service is complete.

Our products are sold with no right of return. Accruals for estimated warranty expenses are provided for at the time the associated revenue is recognized. We use judgment to estimate these accruals and, if we were to experience an increase in warranty claims or if costs of servicing our products under warranty were greater than our estimates, our cost of product revenue could be adversely affected in future periods.

We have entered into license, collaboration and research and development arrangements that generally provide us with up-front and periodic milestone payments. Revenue from license agreements is recognized when payment is received, up-front fees are generally recognized over the term of the agreement, milestone payments are generally recognized when the milestones are achieved, and fees based upon agreed rates for time incurred by our research team are recognized as time is incurred on the project.

Revenue from government grants relates to the achievement of agreed upon milestones and expenditures and is recognized in the period in which the related costs are incurred, provided that the conditions under which the government grants are awarded have been substantially met and only perfunctory obligations remain outstanding. With respect to the EDB grants, upon satisfaction of grant conditions, we received incentive grant payments equal to a portion of qualifying expenses we incurred in Singapore. Qualifying expenses include salaries, overhead, outsourcing and subcontracting expenses, operating expenses and raw material purchases. Royalties paid are not qualifying expenses under the incentive grant program. We submitted requests to the EDB for incentive grant payments on a quarterly basis, which were subject to the EDB s review and our satisfaction of the grant conditions. Our first grant agreement with the EDB was completed in July 2010, at which time we submitted our final progress report and evidence of achievement of our development targets under the letter agreement. In October 2010, we received confirmation from EDB that all of our obligations under the first grant

had been met and, in October 2010, we received our final grant payment relating thereto. Our second grant agreement with the EDB was completed in May 2011. Based on correspondence with EDB, we believe we have satisfied our obligations applicable to our EDB grant revenue through December 31, 2011.

Changes in judgments and estimates regarding application of these revenue recognition guidelines as well as changes in facts and circumstances could result in a change in the timing or amount of revenue recognized in future periods.

#### Stock-Based Compensation

We measure the cost of employee services received in exchange for an award of equity instruments, including stock options and restricted stock units, based on the grant date fair value of the award. The fair value of options on the grant date is estimated using the Black-Scholes option-pricing model, which requires the use of certain subjective assumptions, including expected term, volatility, risk-free interest rate and the fair value of our common stock. These assumptions generally require significant judgment.

Our board of directors sets the terms, conditions and restrictions related to the grant of stock options and restricted stock units, including the number of shares underlying the grants and the vesting criteria. With respect to performance-based stock options, depending on the extent to which the vesting criteria are met, our board of directors determines the number of shares that vest under the grants.

The resulting costs of our equity awards, net of estimated forfeitures, are recognized over the period during which an employee is required to provide service in exchange for the award, usually a time-based vesting period. We amortize the fair value of stock-based compensation on a straight-line basis over the requisite service periods. For performance-based stock options, we recognize stock-based compensation over the requisite service periods using the accelerated attribution method.

We account for stock options issued to nonemployees at their estimated fair value determined using the Black-Scholes option-pricing model. The fair value of the options granted to nonemployees is remeasured as they vest and the resulting change in value, if any, is recognized as expense during the period in which the related services are rendered.

Our common stock has a limited trading history because our common stock was not publicly traded until our initial public offering, or IPO, in February 2011. Accordingly, the expected volatility of our common stock was derived from the historical volatilities of several unrelated public companies within the life science industry. When selecting our industry peer companies, we considered the company stage of development, size and financial leverage. These historical volatilities are weighted based on certain qualitative factors and combined to produce a single volatility factor. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero coupon U.S. Treasury notes with maturities approximately equal to each grant s expected life. We estimate the expected lives of employee options using the simplified method as the midpoint of the expected time-to-vest and the contractual term. For out-of-the-money option grants, we estimate the expected lives based on the midpoint of the expected time to a liquidity event and the contractual term.

The calculated fair value of our stock options could change significantly if we determine that another method is more reasonable, or if another method for calculating these input assumptions is prescribed by authoritative guidance. Higher volatility and longer expected lives result in an increase in stock-based compensation expense determined at the date of grant. Stock-based compensation expense affects our cost of product revenue, research and development expense, and selling, general and administrative expense.

We estimate our forfeiture rate based on an analysis of our actual forfeitures and we will continue to evaluate the appropriateness of the forfeiture rate based on actual forfeiture experience, analysis of employee turnover behavior and other factors. Quarterly changes in the estimated forfeiture rate can have a significant

effect on reported stock-based compensation expense, as the cumulative effect of adjusting the rate for all expense amortization is recognized in the period the forfeiture estimate is changed. If a revised forfeiture rate is higher than the previously estimated forfeiture rate, an adjustment is made that will result in a decrease to the stock-based compensation expense recognized in the consolidated financial statements. If a revised forfeiture rate is lower than the previously estimated forfeiture rate, an adjustment is made that will result in an increase to the stock-based compensation expense recognized in the consolidated financial statements. The effect of forfeiture adjustments was insignificant during 2011, 2010 and 2009. We will continue to use judgment in evaluating the expected term, volatility and forfeiture rate related to our stock-based compensation.

Also required to compute the fair value calculation of options is the fair value of the underlying common stock. We have historically granted stock options with exercise prices no less than the fair value of our common stock as determined at the date of grant by our board of directors with input from management. Prior to our IPO, our board of directors determined the estimated fair value of our common stock based on an analysis of relevant metrics, including contemporaneous valuations of our common stock by an unrelated third-party. The unrelated third-party valuations were prepared using the income or discounted cash flow approach to estimate our aggregate enterprise value at each valuation date. There is inherent uncertainty in these estimates and if we or the valuation firm had made different assumptions, the amount of our stock-based compensation expense, net loss and net loss per share amounts could have been significantly different. Following the completion of our IPO in February 2011, the fair value of options granted is based on the closing price of our common stock on the date of grant as quoted on the NASDAQ Global Market.

Historically, certain of our stock options were granted to officers, with vesting acceleration features based upon the achievement of certain performance milestones. The timing of the attainment of these milestones affected the timing of expense recognition since we recognize compensation expense only for the portion of stock options that are expected to vest.

We recorded stock-based compensation of \$2.8 million, \$1.6 million and \$2.1 million during 2011, 2010 and 2009, respectively. As of December 31, 2011, we had \$6.1 million of unrecognized stock-based compensation costs, which are expected to be recognized over an average period of three years.

#### Accounting for Income Taxes

We use the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Significant management judgment is required in determining our (provision)/benefit for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our deferred tax assets. Our provision for income taxes generally consists of tax expense/benefit related to current period earnings. As part of the process of preparing our consolidated financial statements, we continuously monitor the circumstances impacting the expected realization of our deferred tax assets for each jurisdiction. We consider all available evidence, including historical operating results in each jurisdiction, expectations and risks associated with estimates of future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for a valuation allowance. To the extent a deferred tax asset cannot be recognized, a valuation allowance is established to reduce our deferred tax assets to the amount that is more likely than not to be realized. We have recorded a full valuation allowance on our deferred tax assets due to uncertainties related to our ability to utilize our deferred tax assets in the foreseeable future. These deferred tax assets primarily consist of net operating loss carryforwards and research and development tax credits. We intend to maintain this valuation allowance until sufficient evidence exists to support its reduction. We make estimates and judgments about our future taxable income that are based on assumptions that are consistent with our plans and estimates. Should the actual amounts differ from our estimates, the amount of our valuation allowance could be materially impacted. Changes in these estimates may result in significant increases or decreases to our tax provision in a period in which such estimates are changed, which in turn would affect net income or loss.

We recognize the financial statement effects of a tax position when it is more likely than not, based on the technical merits, that the position will be sustained upon examination. Any interest and penalties related to uncertain tax positions will be reflected in income tax (provision)/benefit.

#### Inventory Valuation

We record adjustments to inventory for potentially excess, obsolete, slow-moving or impaired goods in order to state inventory at its net realizable value. The business environment in which we operate is subject to rapid changes in technology and customer demand. We regularly review inventory for excess and obsolete products and components, taking into account product life cycle and development plans, product expiration and quality issues, historical experience and our current inventory levels. If actual market conditions are less favorable than anticipated, additional inventory adjustments could be required.

#### Warrants to Purchase Convertible Preferred Stock

We accounted for freestanding warrants to purchase shares of our convertible preferred stock as liabilities because the warrants may have conditionally obligated us to transfer assets at some point in the future. The warrants were subject to remeasurement at each balance sheet date, and any change in fair value was recognized as a component of other income (expense), net in the consolidated statements of operations. We estimated the fair value of these warrants at the respective balance sheet dates using the Black-Scholes option-pricing model.

Upon the completion of our IPO in February 2011, a portion of these outstanding warrants converted into warrants to purchase common stock. The remainder of the warrants either expired or were net exercised for shares of our common stock and the related liability was reclassified to additional paid-in-capital.

#### **Results of Operations**

#### Revenue

We generate revenue from sales of our products, license and collaboration agreements and government grants. Our product revenue consists of sales of instruments and related services, and consumables, including chips, assays and other reagents. We have entered into license and collaboration agreements and research and development contracts, and have received government grants to conduct research and development activities.

The following table presents our revenue by source for each period presented (in thousands).

	Yea	Year Ended December 31,			
	2011	2010	2009		
Revenue:					
Instruments	\$ 25,190	\$ 20,708	\$ 17,318		
Consumables	15,391	9,754	6,281		
Product revenue	40,581	30,462	23,599		
License and collaboration revenue	1,716	1,625			
Grant revenue	568	1,473	1,813		
Total revenue	\$ 42,865	\$ 33,560	\$ 25,412		

The following table presents our product revenue by geography and as a percentage of total product revenue by geography based on the billing address of our customers for each period presented (in thousands).

		Year Ended December 31,				
	2011	2011		2010		9
United States	\$ 21,644	53%	\$ 16,619	55%	\$ 12,630	54%
Europe	10,499	26%	7,577	25%	4,885	21%
Japan	3,942	10%	2,700	9%	3,172	13%
Asia-Pacific	3,698	9%	2,800	9%	2,162	9%
Other	798	2%	766	2%	750	3%
Total	\$ 40,581	100%	\$ 30,462	100%	\$ 23,599	100%

Grant revenue is received from our incentive grants with the EDB and the California Institute of Regenerative Medicine, or CIRM. License and collaboration revenue is primarily generated in the United States. As we expand our business internationally, we expect our product revenue from outside of the United States to increase as a percentage of our total product revenue.

Our customers include academic research institutions, diagnostic laboratories, and pharmaceutical, biotechnology and Ag-Bio companies worldwide. Total revenue from our five largest customers in each of the periods presented comprised 16%, 19% and 20% of revenue in 2011, 2010 and 2009, respectively.

#### Comparison of the Years Ended December 31, 2011 and December 31, 2010

#### **Total Revenue**

Total revenue increased by \$9.3 million, or 28%, to \$42.9 million for 2011 as compared to \$33.6 million for 2010.

#### **Product Revenue**

Product revenue increased by \$10.1 million, or 33%, to \$40.6 million for 2011 as compared to \$30.5 million for 2010, reflecting increased revenue from sales of instruments and consumables. Consumables revenue increased by \$5.6 million, or 58%, resulting from our higher installed base of instruments and the launch of our assays business in the first half of 2011. Instrument revenue increased by \$4.5 million, or 22%, resulting from an increase in instrument sales volume of 19%, primarily driven by sales of our Access Array instrument. Average instrument selling prices were higher for 2011 compared to 2010 due to the launch of our BioMark HD system in the first quarter of 2011, which has a higher average selling price than our other systems, and increased sales in Japan and Europe, where average selling prices are higher, partially offset by increased sales of our Access Array systems, which has a lower average selling price compared to our BioMark and EP1 systems.

We expect unit sales of both instruments and consumables to continue to increase in future periods as we continue our efforts to grow our customer base and expand our geographic market coverage. However, we expect the average selling prices of our instruments to fluctuate over time based on product mix.

#### License and Collaboration Revenue

License and collaboration revenue was \$1.7 million for 2011 compared to \$1.6 million for 2010, primarily related to a fixed-fee research and development collaboration agreement (the agreement or arrangement) that we entered into in May 2010. The arrangement provided for an up-front fee of \$0.7 million that was recognized on a straight-line basis over the estimated period of performance under the agreement. In March 2011, we amended the agreement and received an additional \$0.3 million payment. Under the amendment, certain milestones and the payment terms associated with satisfaction of the milestones were modified. The \$0.7 million up-front

payment and the \$0.3 million payment received in March 2011 were being recognized on a straight-line basis through September 30, 2011, which was management s best estimate of its period of performance under the amended agreement. During July 2011, we reassessed the period of performance and extended it through November 2011. This change in estimate did not have a material impact on the recognition of the remaining deferred revenue under the agreement.

The arrangement also provided for milestone payments for the design and development of product prototypes, which have been recognized as we achieved each milestone. During 2011, we achieved three milestones, submitted our final report under the agreement, and recognized \$1.0 million of milestone revenue. During 2010, we achieved three milestones and recognized \$1.25 million of milestone revenue. All of our performance obligations under the agreement were completed at December 31, 2011. We may receive additional payments if and when we finalize our on-going negotiations with our partner for the next phase of the agreement. We cannot predict the outcome of these negotiations.

#### **Grant Revenue**

Grant revenue consists of incentive grants from government entities, including EDB and CIRM. Grant revenue decreased \$0.9 million to \$0.6 million for 2011 compared to \$1.5 million for 2010. The decrease relates to a reduction in activity under the EDB grant agreements as we achieved certain milestones and reached the end of the grant periods, partially offset by new grant revenue from CIRM. Under our incentive grant agreements with EDB, we received incentive grant payments equal to a portion of qualifying expenses we incurred in Singapore. Qualifying expenses incurred by us in Singapore were \$0.5 million in 2011 and \$3.8 million in 2010.

Our agreements with EDB provided that grants extended to us were subject to certain grant conditions, including increasing our levels of research, development and manufacturing in Singapore through the use of local service providers, the hiring and training of personnel in Singapore, the incurrence of research and development expenses in Singapore, receipt of new investment in our company and the achievement of certain agreed upon milestones relating to the development of our products. Development and manufacturing milestones achieved include completion of feasibility studies and prototype development, establishment of manufacturing lines, process automation and manufacturing yield improvements for our chips and related instruments. These agreements further provided EDB with the right to demand repayment of a portion of past grants in the event that we did not meet our obligations under the applicable agreements. Based on correspondence with EDB, we believe we have satisfied our obligations applicable to our EDB grant revenue through December 31, 2011. Our first grant agreement with the EDB was completed in July 2010. In October 2010, we received confirmation from EDB that all of our obligations under the first grant had been met and, in October 2010, we received our final grant payment relating thereto. Our second grant agreement with the EDB was completed in May 2011. Based on correspondence with EDB, we believe we have satisfied our obligations applicable to our BDB grant revenue through December 31, 2011.

Our first CIRM grant was awarded in 2009 in the amount of \$0.8 million to be earned over a two-year period. Our second CIRM grant was awarded in 2011 in the amount of \$1.9 million to be earned over a three-year period. The CIRM grant revenue is recognized as the related research and development services are performed and costs associated with the grants are recognized as research and development expense during the period incurred.

We expect total grant revenue for 2012 and future periods to decrease compared to 2011 as our EDB agreements were completed during 2010 and 2011. This decrease is partially offset by grant revenue from CIRM for us to design and develop prototype microfluidic systems for use in stem cell research.

#### Cost of Product Revenue

The following table presents our cost of product revenue and product margin for each period presented (in thousands).

	Year	Year Ended			
	December 31, 2011	Dec	ember 31, 2010		
Cost of product revenue	\$ 13,191	\$	11,581		
Product margin	67%		62%		

Cost of product revenue includes manufacturing costs incurred in the production process, including component materials, assembly labor and overhead, installation, warranty, service and packaging and delivery costs. In addition, cost of product revenue includes royalty costs for licensed technologies included in our products, provisions for slow-moving and obsolete inventory and stock-based compensation expense. Costs related to license, collaboration and grant revenue are included in research and development expense.

Cost of product revenue increased \$1.6 million, or 14%, to \$13.2 million for 2011 from \$11.6 million for 2010 due to increased product sales in 2011. Cost of product revenue as a percentage of related revenue decreased to 33% for 2011 compared to 38% for 2010. This decrease was primarily due to lower instrument component costs and higher instrument average selling prices, and, to a lesser extent, lower chip manufacturing costs.

# **Operating Expenses**

The following table presents our operating expenses for each period presented (in thousands):

	Year	Year Ended				
	December 31, 2011	Dec	ember 31, 2010			
Research and development	\$ 13,936	\$	13,007			
Selling, general and administrative	31,304		23,545			
Litigation settlement	3,000					
Total operating expenses	\$ 48,240	\$	36,552			

#### **Research and Development**

Research and development expense consists primarily of personnel costs, independent contractor costs, prototype and material expenses and other allocated facilities and information technology expenses. We have made substantial investments in research and development since our inception. Our research and development efforts have focused primarily on enhancing our technologies and to support development and commercialization of new and existing products and services.

Research and development expense increased \$0.9 million, or 7%, to \$13.9 million for 2011 compared to \$13.0 million for 2010. The increase relates primarily to increased lab supplies and consumables of \$0.6 million, consulting and professional fees of \$0.2 million to support our new product development, and increased compensation and personnel related costs of \$0.3 million, which include stock based compensation, partially offset by lower equipment and depreciation expense of \$0.2 million.

We believe that our continued investment in research and development is essential to our long-term competitive position and these expenses may increase in future periods.

#### Selling, General and Administrative

Selling, general and administrative expense consists primarily of personnel costs for our sales and marketing, business development, finance, legal, human resources and general management, as well as professional services, such as legal and accounting services.

Selling, general and administrative expense increased \$7.8 million, or 33%, to \$31.3 million for 2011, compared to \$23.5 million for 2010. The increase was primarily due to increased compensation costs and related expenses, including stock-based compensation, of \$5.4 million, resulting from increased headcount to support our business and revenue growth, increased legal and professional fees of \$1.7 million, increased other costs of \$1.0 million to support our public company requirements and increased advertising and promotional costs of \$0.4 million to support our new product introductions and to increase market awareness of our products, partially offset by lower rent expense of \$0.4 million resulting from our lease renewal on more favorable terms for our headquarters facility in South San Francisco, California and a decrease in our provision for bad debt expense of \$0.3 million.

We expect selling, general and administrative expense to increase in future periods as we continue to grow our sales, technical support, marketing and administrative headcount, support increased product sales, broaden our customer base and incur additional costs to support our expanded global footprint and the overall growth in our business. We also expect legal, accounting and compliance costs to increase as a result of being a public company.

# Litigation Settlement

On June 30, 2011, we settled certain litigation and entered into a series of patent license agreements resulting in a net \$3.0 million payment by us to Life Technologies Corporation and its Applied Biosystems, LLC subsidiary, referred to as Life. The payment was recognized as litigation settlement expense in our consolidated statement of operations because the amount paid by us was principally attributable to resolving Life s litigation claims against us with respect to a specific expiring U.S. patent and its foreign counterparts.

Under the terms of the agreements, each party had the option, exercisable for thirty days from the date of the agreements, to limit or preclude certain patent litigation between the parties over a period of two to four years. These rights were subject to certain exceptions and required an additional payment by the party exercising the option at the time of exercise. In July 2011, we exercised our option and paid Life \$2.0 million. As a result, subject to certain exceptions, Life may not initiate litigation under its patents existing as of June 30, 2011 against our customers for two years and against us, with respect to our current products and equivalent future products, for four years. The additional payment was recorded in other assets and is being amortized to selling, general and administrative expense over four years on a straight-line basis beginning in July 2011. The additional payment is being amortized to selling, general and administrative expense because it precludes Life from initiating litigation under its relevant patents for any alleged prior and future infringement by us for four years, and because such preclusion relates to our equivalent future products. Life elected not to exercise its option.

Litigation settlement expense increased \$3.0 million for 2011 as a result of the agreements entered into with Life on June 30, 2011. We had no similar agreement in 2010.

#### Interest Expense, Interest Income and Other Income and Expense, Net

We receive interest income from our cash and cash equivalents and investments. Conversely, we incur, or have incurred, interest expense from our long-term debt, bank line of credit and convertible promissory notes, and the amortization of debt discounts related to these items. Until the completion of our IPO, we also recognized income or expense as a result of changes in the fair value of outstanding warrants to purchase shares of our convertible preferred stock. The following table presents these items for each period presented (in thousands).

	Year Ended		
	December 31, Decem		ember 31, 2010
Interest expense	\$ (3,101)	\$	(2,158)
Loss from changes in the fair value of convertible preferred			
stock warrants, net	(1,483)		(445)
Gain from expiration of unexercised warrants	765		
Other income, net	81		357
Deemed dividend related to the change in conversion rate of			
Series E convertible preferred stock	(9,900)		

Interest expense increased \$0.9 million, or 44%, to \$3.1 million for 2011 compared to \$2.2 million for 2010. The increase is primarily due to \$1.2 million of non-cash interest expense in connection with a \$5.0 million note and warrant purchase agreement entered into in January 2011. We repaid all principal and interest outstanding under the notes in February 2011 upon the completion of our IPO. There was no similar transaction or recognition of expense in 2010. We expect interest expense to decrease in 2012 compared to 2011 as we repay our outstanding debt.

Losses from changes in the fair value of preferred stock warrants increased \$1.1 million to \$1.5 million for 2011 from \$0.4 million for 2010 due to an increase in the warrant liability fair value through the completion of our IPO on February 15, 2011. Upon completion of our IPO, our outstanding preferred stock warrants converted into warrants to purchase common stock or expired unexercised. A portion of the preferred stock warrants that converted into warrants to purchase common stock were net exercised in connection with our IPO. Liabilities related to the expired warrants were reversed and resulted in a gain reflected in other income. Liabilities related to the warrants that were converted into warrants to purchase common stock were reclassified to additional paid-in-capital.

Other income, net decreased from \$0.4 million in 2010 to \$0.1 million for 2011, a decrease of 77%, to primarily due to unfavorable changes in foreign currency exchange gains and losses partially offset by an increase in interest income due to the increase in our cash, cash equivalents and investments during 2011.

#### Deemed Dividend

In January 2011, we amended and restated our certificate of incorporation to decrease the conversion price of our Series E convertible preferred stock from \$24.22 to \$18.63 per share. As a result, we recognized a deemed dividend of \$9.9 million, reflecting the fair value of the additional shares of common stock to be issued as a result of the change in conversion price of the Series E convertible preferred stock. The deemed dividend increased the net loss attributed to common stockholders in the calculation of basic and diluted net loss per share.

#### Comparison of the Years Ended December 31, 2010 and December 31, 2009

#### **Total Revenue**

Total revenue increased by \$8.1 million, or 32%, to \$33.6 million for 2010 as compared to \$25.4 million for 2009.

#### **Product Revenue**

Product revenue increased by \$6.9 million, or 29%, to \$30.5 million for 2010 as compared to \$23.6 million for 2009, reflecting increased revenue from sales of instruments and consumables. Consumables revenue increased by \$3.5 million, or 55%, resulting from our higher installed base of instruments. Instrument revenue increased by \$3.4 million, or 20%, resulting from an increase in instrument sales volume of 48%, primarily driven by sales of our Access Array instrument, which was launched in the second half of 2009. Although the volume of our instrument sales increased in 2010, average instrument selling prices were lower for 2010 compared to 2009 due to increased sales of our Access Array instrument, which has a lower average selling price compared to our BioMark and EP1 instruments.

#### **Collaboration Revenue**

Collaboration revenue was \$1.6 million for 2010, resulting from a fixed-fee research and development collaboration agreement (the agreement or the arrangement) that we entered into in May 2010. The arrangement provided for an up-front fee of \$0.7 million that was recognized on a straight-line basis over the estimated period of performance under the agreement. The arrangement also provided for milestone payments for the design and development of product prototypes, which were recognized as we achieved each milestone. In 2010, we achieved three milestones and received three milestone payments totaling \$1.25 million. In 2009, we did not have any research and development arrangements in place.

#### **Grant Revenue**

Grant revenue consists of incentive grants from government entities, primarily EDB. Grant revenue decreased \$0.3 million, or 19%, to \$1.5 million for 2010 compared to \$1.8 million for 2009. The decrease relates to a reduction in activity under the EDB grant agreement as we reached certain milestones. Under our incentive grant agreements with EDB, we received incentive grant payments equal to a portion of qualifying expenses we incurred in Singapore. Qualifying expenses incurred by us in Singapore were \$3.8 million in 2010 and \$3.7 million in 2009.

Our agreements with EDB provide that grants extended to us are subject to certain grant conditions, including increasing our levels of research, development and manufacturing in Singapore through the use of local service providers, the hiring and training of personnel in Singapore, the incurrence of research and development expenses in Singapore, receipt of new investment in our company and the achievement of certain agreed upon milestones relating to the development, establishment of manufacturing lines, process automation and manufacturing yield improvements for our chips and related instruments. These agreements further provided EDB with the right to demand repayment of a portion of past grants in the event that we did not meet our obligations under the applicable agreements. Based on correspondence with EDB, we believe we have satisfied our obligations applicable to our EDB grant revenue through December 31, 2010.

#### Cost of Product Revenue

The following table presents our cost of product revenue and product margin for each period presented (in thousands).

	Year	Year Ended			
	December 31, 2010	December 31, 2009			
Cost of product revenue	\$ 11,581	\$	11,486		
Product margin	62%		51%		

Cost of product revenue includes manufacturing costs incurred in the production process, including component materials, assembly labor and overhead, installation, warranty, service and packaging and delivery costs. In addition, cost of product revenue includes royalty costs for licensed technologies included in our products, provisions for slow-moving and obsolete inventory and stock-based compensation expense. Costs related to collaboration and grant revenue are included in research and development expense.

Cost of product revenue increased \$0.1 million, or 1%, to \$11.6 million for 2010 from \$11.5 million for 2009 due to increased product sales in 2010. Cost of product revenue as a percentage of related revenue decreased to 38% for 2010 compared to 49% for 2009. This decrease was primarily due to lower material costs for our instruments as we sourced more components from local vendors in Asia. In addition, our overhead costs increased more slowly relative to our increase in revenue resulting in improved absorption, improved chip yields and lower costs for our chips.

#### **Operating Expenses**

The following table presents our operating expenses for each period presented (in thousands):

	Year	Year Ended			
	December 31, 2010	December 31, 2009			
Research and development	\$ 13,007	\$ 12,315			
Selling, general and administrative	23,545	19,648			
Total operating expenses	\$ 36,552	31,963			

#### **Research and Development**

Research and development expense consists primarily of personnel costs, independent contractor costs, prototype and material expenses and other allocated facilities and information technology expenses. We have made substantial investments in research and development since our inception. Our research and development efforts have focused primarily on enhancing our technologies and to support development and commercialization of new and existing products and services.

Research and development expense increased \$0.7 million, or 6%, to \$13.0 million for 2010 compared to \$12.3 million for 2009. The increase relates primarily to increased compensation and personnel related costs of \$0.6 million and increased consumption of lab supplies and consumables of \$0.3 million to support our new product development, partially offset by a one-time payment of \$0.2 million awarded under the U.S. Government s Therapeutic Discovery Project.

#### Selling, General and Administrative

Selling, general and administrative expense consists primarily of personnel costs for our sales and marketing, business development, finance, legal, human resources and general management, as well as professional services, such as legal and accounting services.

Selling, general and administrative expense increased \$3.9 million, or 20%, to \$23.5 million for 2010, compared to \$19.6 million for 2009. The increase was primarily due to increased compensation costs and related expenses of \$2.3 million resulting from increased headcount to support our business and revenue growth, increased advertising and promotional costs of \$0.8 million to support our new product introductions and to increase market awareness of our products, increased legal and professional fees of \$0.7 million, and an increase in our provision for bad debt expense of \$0.2 million, partially offset by lower rent expense of \$0.1 million resulting from our new lease on more favorable terms for our headquarters facility in South San Francisco, California.

#### Interest Expense, Interest Income and Other Income and Expense, Net

We receive interest income from our cash and cash equivalents. Conversely, we incur interest expense from our long-term debt, bank line of credit and convertible promissory notes, and the amortization of debt discounts related to these items. The following table presents these items for each period presented (in thousands).

	Year Ended			
	December 31, 2010	Dec	ember 31, 2009	
Interest expense	\$ (2,158)	\$	(2,876)	
Loss from changes in the fair value of convertible preferred				
stock warrants, net	(445)		(135)	
Other income, net	357		1,870	

Interest expense decreased \$0.7 million, or 25%, to \$2.2 million for 2010 compared to \$2.9 million for 2009 due to the conversion of \$10.7 million in convertible promissory notes in November 2009. In connection with the conversion, the entire \$0.7 million discount on the debt was immediately recognized as interest expense in 2009. There was no similar transaction or recognition of expense in 2010.

Losses from changes in the fair value of preferred stock warrants increased \$0.3 million to \$0.4 million for 2010 from \$0.1 million for 2009 due to an increase in the warrant liability fair value.

Other income, net decreased from \$1.9 million in 2009 to \$0.4 million for 2010, a decrease of 81%, primarily due to income recognized in 2009 from a sub-license arrangement, partially offset by favorable changes in foreign currency exchange gains and losses.

#### Liquidity and Capital Resources

#### Sources of Liquidity

As of December 31, 2011, we had \$13.6 million of cash and cash equivalents and \$41.4 million of investments. As of December 31, 2011, our working capital totaled \$49.9 million. In February 2011, we completed our IPO which resulted in proceeds to us of approximately \$77.0 million, net of underwriting discounts, commissions and offering expenses. Following the completion of our IPO, we paid the balance on our bank line of credit of \$3.1 million, which is collateralized by our accounts receivable and provides us the ability to borrow up to \$7.0 million, subject to certain covenants and other restrictions, and paid \$5.0 million to satisfy all outstanding principal and interest on the notes we issued in January 2011.

Prior to our IPO, we funded our operations principally through issuances of convertible preferred stock, which provided us with aggregate net proceeds of \$184.6 million, of which \$30.7 million was in the form of convertible promissory notes that converted into convertible preferred stock. We also received significant funding in the form of non-convertible loans that provided us with aggregate net proceeds of \$26.6 million. As of December 31, 2011, we had an accumulated deficit of \$221.8 million.

We have received funding in the form of grants from government entities. Most significantly, we have received grants from the EDB that helped support the establishment and operation of our Singapore manufacturing, and research and development facilities.

Our first grant agreement with the EDB was completed in July 2010 and our second grant agreement with the EDB was completed in May 2011. Our first grant with CIRM was awarded in 2009 for \$0.8 million to be recognized over a two-year period and our second grant with CIRM was awarded in 2011 for \$1.9 million to be recognized over a three-year period.

To maintain eligibility for grant payments under our second grant agreement, we were required to incur annual spending in Singapore of at least SG\$9.0 million (approximately US\$6.5 million) for the 12 months ending May 31, 2011. For this purpose, spending in Singapore includes overhead, salaries, outsourcing and subcontracting expenses, operating expenses and royalties paid, with limited exceptions such as raw materials purchases. Expenditures that are used to satisfy the requirements of one grant agreement are not eligible for satisfaction of the other grant agreement. To qualify for payment under the second grant agreement, expenditures must relate to the development of instrumentation for our systems and not our chips.

Our second grant agreement also required that we employ at least 12 new research scientists and engineers in Singapore by May 31, 2011, which may only be satisfied by personnel employed in the research and development of our instruments. In addition, we are required to employ at least 12 research scientists and engineers until May 31, 2013, which may be satisfied by personnel employed in the research and development of either chips or instruments. As of December 31, 2011, we employed 14 research scientists and engineers involved in the research and development of our chips and 7 research scientists and engineers involved in the research and development of related instrumentation in Singapore. As of December 31, 2011, we have received \$7.0 million in grant payments from the EDB under our grant agreements. We have not entered into additional grant agreements with the EDB. In the event that we do not receive grant funding from EDB in the future, we do not believe that our liquidity would be materially affected.

We have entered into multiple convertible note purchase agreements with Biomedical Sciences Investment Fund Pte. Ltd., or BMSIF, pursuant to which we issued convertible notes and received proceeds in the amount of \$21.6 million. BMSIF is wholly-owned by EDB Investments Pte. Ltd., whose parent entity is the EDB. Ultimately, each of these entities is controlled by the government of Singapore. All of the convertibles notes converted into shares of our Series E convertible preferred stock in or before November 2009. As of December 31, 2011, there were no outstanding principal and accrued interest balances for our convertible note purchase agreements with BMSIF.

In March 2005, we entered into a loan and security agreement with a lender under which we borrowed \$13.0 million with an interest rate of 11.5% per annum and maturity date in February 2010. The loan and security agreement was amended in February 2008 to provide us with an additional credit line in the amount of \$10.0 million, which was fully drawn down in June 2008. We made monthly interest only payments through the remainder of 2008 and began making monthly payments of principal and interest in the amount of \$0.4 million in January 2009. The agreement required a final payment in the amount of \$0.7 million in June 2011, which was accreted as interest expense over the term of the loan.

In March 2009, we combined and restructured the loan and security agreement. The restructured loan and security agreement had a final repayment date of March 1, 2012 with an interest rate of 13.5% per annum. We made monthly interest only payments through February 1, 2010 and began making monthly principal and interest payments of \$0.6 million in March 2010. The restructured loan agreement required a final payment in the amount of \$2.1 million and payment of fees in the amount of \$0.2 million in March 2012, which were accreted as interest expense over the term of the loan. In connection with the restructuring, we issued to the lender a warrant to purchase 41,288 shares of Series E convertible preferred stock at \$24.22 per share. The fair value of the warrant resulted in a debt discount that is being amortized to interest expense over the life of the agreement.

In June 2010, we amended the restructured loan and security agreement discussed above to provide for maturity in February 2013 and an interest rate of 13.5% per annum. We made interest only payments through February 2011 and began making monthly principal and interest payments of \$0.6 million in March 2011 with the additional payment of \$2.3 million due in March 2012. The terms relating to the additional payment and fees payable in March 2012 remained the same. In connection with the execution of this loan and security agreement, we issued to the lender a warrant to purchase 57,784 shares of Series E-1 convertible preferred stock at \$12.11 per share. The fair value of the warrant resulted in a debt discount that is being amortized to interest expense over the life of the agreement. In addition, we amended warrants previously issued to this lender by reducing the

exercise price of all of the lender s warrants to \$12.11 per share and extending the term of one warrant. The warrants were revalued as a result of the warrant amendments, resulting in a \$0.1 million increase in value. The increased value resulted in an additional debt discount that will be amortized to interest expense over the life of the agreement.

Upon completion of our IPO in February 2011, all 209,960 warrants to purchase shares of convertible preferred stock that were held by the lender were converted to warrants to purchase shares of common stock. In July 2011, the lender net exercised all the warrants for an exercise price of \$12.11 and was issued 70,731 shares of common stock.

As of December 31, 2011, the outstanding principal and accrued interest balance under the loan and security agreement was \$10.1 million, net of unamortized debt discounts of \$0.1 million.

During 2010, we offered holders of preferred stock warrants with an exercise price over \$12.11 per share the opportunity to amend those warrants to lower the exercise price to \$12.11 per share. The amended warrants would be exercisable for Series E-1 convertible preferred stock and would receive one common share for each preferred share purchased, subject to the warrant holder s agreement to immediately exercise the warrants in full and for cash. The offer expired in August 2010 with warrants to purchase 57,724 shares of preferred stock exercised. As a result of this offer, we received gross proceeds of \$0.7 million and issued 57,724 shares of both Series E-1 convertible preferred stock and common stock. The rights, preferences, and other terms of the Series E-1 convertible preferred stock were identical to those of our Series E convertible preferred stock, except the liquidation preference of the Series E-1 convertible preferred stock was \$12.11 per share.

On February 10, 2011, we had outstanding warrants to purchase a total of 489,880 shares of our convertible preferred stock. The fair value of these warrants was approximately \$3.7 million at February 10, 2011, which was an increase in fair value of approximately \$1.5 million since December 31, 2010. Upon the closing of our IPO, warrants to purchase 103,182 shares were net exercised and the related liability of \$1.4 million was reclassified to additional paid-in capital. Warrants to purchase 209,960 shares were converted into warrants to purchase shares of our common stock and the related liability of \$1.5 million was reclassified to additional paid-in capital. The remaining warrants to purchase 176,738 shares expired unexercised and the related liability of \$0.8 million was recognized as other income.

The following table presents our cash flow summary for each period presented (in thousands):

	Year	Year Ended December 31,			
	2011	2010	2009		
Cash flow summary					
Net cash used in operating activities	\$ (17,542)	\$ (11,508)	\$ (19,513)		
Net cash used in investing activities	(45,110)	(1,333)	(688)		
Net cash provided by financing activities	70,367	3,797	16,939		
Net increase (decrease) in cash and cash equivalents	7,830	(8,879)	(3,194)		

#### Net Cash Used in Operating Activities

We derive cash flows from operations primarily from cash collected from the sale of our products, collaboration and license agreements and grants from certain government entities. Our cash flows from operating activities are also significantly influenced by our use of cash for operating expenses to support the growth of our business. We have historically experienced negative cash flows from operating activities as we have expanded our business and built our infrastructure domestically and internationally and this may continue in the future.

Net cash used in operating activities was \$17.5 million, \$11.5 million and \$19.5 million in 2011, 2010 and 2009, respectively. Net cash used in operating activities during 2011 primarily consisted of our net loss of \$22.5 million and changes in our operating assets and liabilities in the amount of \$1.0 million, offset by non-cash items

of \$5.9 million, including stock-based compensation of \$2.8 million, loss from changes in the fair value of convertible preferred stock warrants of \$1.5 million, depreciation and amortization of our property and equipment of \$1.1 million, write offs of debt discounts of \$1.2 million upon repayment of notes, and amortization of debt discounts and issuance cost of \$0.2 million, and a gain from extinguishment of convertible preferred stock warrants of \$0.8 million.

Net cash used in operating activities of \$11.5 million during 2010 primarily consisted of our net loss of \$16.9 million, offset by changes in our operating assets and liabilities in the amount of \$1.9 million, and non-cash expense items of \$3.5 million including stock-based compensation of \$1.6 million, depreciation and amortization of our property and equipment of \$1.1 million, loss from changes in the fair value of convertible preferred stock warrants of \$0.4 million, and amortization of debt discounts and issuance cost of \$0.4 million.

Net cash used in operating activities of \$19.5 million during 2009 primarily consisted of our net loss of \$19.1 million and changes in our operating assets and liabilities in the amount of \$2.7 million, offset by non-cash items of \$2.3 million, including stock-based compensation of \$2.1 million, loss from changes in the fair value of convertible preferred stock warrants of \$0.1 million, depreciation and amortization of our property and equipment of \$1.6 million, amortization of debt discount and issuance costs of \$0.3 million, gain from sublicense of technology of \$1.8 million and gain on sales of property and equipment of \$0.1 million.

#### Net Cash Used in Investing Activities

Historically, our primary investing activities have consisted of capital expenditures for laboratory, manufacturing and computer equipment and software to support our expanding infrastructure and work force; restricted cash related to leased space and lending agreements; and purchases, sales and maturities of our investments. We expect to continue to expand our manufacturing capability, which is located primarily in Singapore, including improvements in manufacturing productivity, and expect to incur additional costs for capital expenditures related to these efforts in future periods. In addition, we expect to incur costs for capital expenditures for demonstration units and loaner equipment to support our sales and service efforts.

Net cash used in investing activities was \$45.1 million, \$1.3 million and \$0.7 million in 2011, 2010 and 2009, respectively. Net cash used in investing activities during 2011 primarily consisted of purchases of marketable securities, net of maturities and sales, of \$41.4 million; capital expenditures of \$1.7 million to support our infrastructure, including information technology, and manufacturing operations; and license agreement rights under our settlement with Life of \$2.0 million.

We used \$1.3 million of cash in investing activities during 2010 for purchases of capital equipment to support our infrastructure and manufacturing operations of \$1.5 million, partially offset by the release of \$0.2 million from restricted cash for a sub-lease that expired and from a lower restricted cash requirement on the new lease for our headquarters facility in South San Francisco, California.

We used \$0.7 million of cash in investing activities during 2009 for purchases of capital equipment to support our infrastructure and manufacturing operations of \$0.8 million, partially offset by proceeds of \$0.1 million from disposals of property and equipment.

#### Net Cash Provided by Financing Activities

Prior to our IPO, we funded our operations principally through issuances of convertible preferred stock and long-term debt.

We generated \$70.4 million of cash from financing activities during 2011 primarily from net proceeds of \$77.0 million, net of underwriting discounts, commissions and offering expenses and proceeds from the exercise of stock options of \$1.3 million, partially offset by principal payments on our long-term debt of \$4.7 million and repayment of our bank line of credit balance of \$3.1 million.

We generated \$3.8 million of cash from financing activities during 2010 primarily from proceeds from our line of credit of \$3.1 million and proceeds from exercises of preferred stock warrants and stock options of \$0.7 million.

We generated \$16.9 million of cash from financing activities during 2009 primarily from proceeds from the issuance of convertible promissory notes, net of issuance costs, of \$10.5 million and proceeds from the issuance of convertible preferred stock, net of issuance costs, of \$7.4 million, partially offset by principal payments on our long-term debt of \$1.0 million.

#### **Capital Resources**

At December 31, 2011, December 31, 2010 and December 31, 2009, our working capital was \$49.9 million, \$2.4 million and \$21.4 million, respectively, including cash and cash equivalents of \$13.6 million, \$5.7 million and \$14.6 million, respectively, and investments of \$41.4 million at December 31, 2011. In December 2010, we entered into a bank line of credit agreement that is collateralized by our accounts receivable and provides us the ability to draw up to \$7.0 million, subject to certain covenants and restrictions. In January 2011, we raised \$5.0 million through the issuance of subordinated secured promissory notes and warrants to our existing stockholders. In February 2011, we raised approximately \$77.0 million, net of underwriting discounts, commissions and offering expenses. In February and March 2011, we repaid the \$5.0 million in promissory notes issued by us in January 2011. Beginning in March 2011, we began making principal payments on our long-term debt, following the end of the interest-only period in February 2011. Commencing in March 2011, monthly payments increased from interest payments of \$0.2 million to principal and interest payments of \$0.6 million. Principal payments on our long-term debt were \$4.7 million, \$0 and \$1.0 million in 2011, 2010 and 2009. In 2012, we expect principal payments to be significantly higher, at \$9.0 million, including a balloon payment of \$2.3 million. During 2011, 2010 and 2009, our capital expenditures were \$1.7 million, \$1.5 million and \$0.8 million, respectively. We are estimating capital expenditures to be higher in 2012 primarily for research and development equipment to continue our improvements in manufacturing productivity and sales demonstration and loaner equipment to service the growth in our global customer base.

We believe our existing cash and cash equivalents, including the net proceeds from our IPO, will be sufficient to meet our working capital and capital expenditure needs for at least the next 18 months. However, we may experience lower than expected cash generated from operating activities or greater than expected capital expenditures, cost of revenue or operating expenses, and we may need to raise additional capital to expand the commercialization of our products, expand and fund our operations and further our research and development activities. Our future funding requirements will depend on many factors, including market acceptance of our products, the cost of our research and development activities, the cost of filing and prosecuting patent applications, the cost of defending, in litigation or otherwise, any claims that we infringe third-party patents or violate other intellectual property rights, the cost and timing of regulatory clearances or approvals, if any, the cost and timing of establishing additional sales, marketing and distribution capabilities, the cost and timing of establishing additional technical support capabilities, and the effect of competing technological and market developments. In the future, we may acquire businesses or technologies from third parties, and we may decide to raise additional capital through debt or equity financing to the extent we believe this is necessary to successfully complete these acquisitions. We currently have no commitments or agreements relating to any such acquisitions.

If we require additional funds in the future, we may not be able to obtain such funds on acceptable terms, or at all. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any debt or additional equity financing that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us. If we are unable to raise adequate funds, we may have to liquidate some or all of our assets, or delay, reduce the scope of or eliminate some or all of our development programs. If we do not have, or are not able to obtain, sufficient funds, we may have to delay development or commercialization of our products or

license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize. We also may have to reduce marketing, customer support, research and development, or other resources devoted to our products or cease operations.

#### **Off-Balance Sheet Arrangements**

Since our inception, we have not had any off-balance sheet arrangements as defined in Item 303(a)(4) of the Securities and Exchange Commission s Regulation S-K.

#### **Contractual Obligations and Commitments**

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

	Payments Due by Period Less than 1				
	Total	Year	1-3 Years	3-5 Years	Thereafter
Long-term debt	\$ 10,190	\$ 8,972	\$ 1,218	\$	\$
Operating lease obligations	3,800	1,302	2,217	281	
Purchase obligations	4,245	4,245			
Total	\$ 18,235	\$ 14,519	\$ 3,435	\$ 281	\$

Our operating lease obligations relate to a lease for our current headquarters and leases for office space for our foreign subsidiaries. Purchase obligations consist of contractual and legally binding commitments to purchase goods.

We have entered into several license and patent agreements. Under these agreements, we pay annual license maintenance fees, nonrefundable license issuance fees, and royalties as a percentage of net sales for the sale or sublicense of products using the licensed technology. If we elect to maintain these license agreements, we will pay aggregate annual fees of \$0.3 million per year until 2027. Future payments related to these license agreements have not been included in the contractual obligations table above as the period of time over which the future license payments will be required to be made, and the amount of such payments are indeterminable.

On March 7, 2003 we entered into a Master Closing Agreement with Oculus Pharmaceuticals, Inc. and the UAB Research Foundation, or UAB, related to certain intellectual property and technology rights licensed by us from UAB. Pursuant to the agreement, we are obligated to issue UAB shares of our common stock with a value equal to \$1.5 million upon the achievement of a certain milestone and based upon the fair market value of our common stock at the time the milestone is achieved. We currently do not anticipate achieving this milestone in the foreseeable future and do not anticipate issuing these shares.

In September 2010, we entered into a new lease for our headquarters in South San Francisco, California. The new lease expires in April 2015 and includes a renewal option for an additional three years. We received a \$0.4 million lease incentive which is being recognized as a reduction of rent expense on a straight-line basis over the term of the new lease.

#### **Recent Accounting Pronouncements**

#### Fair Value Measurement

In May 2011, the FASB issued changes to conform existing guidance regarding fair value measurement and disclosure between U.S. GAAP and International Financial Reporting Standards. This guidance clarifies the application of existing fair value measurements and disclosures, and changes certain principles or requirements for fair value measurements and disclosures. The amendment is effective for interim and annual periods beginning after December 15, 2011 and will be applied prospectively. We are currently evaluating the impact on our consolidated financial statements of adopting these amendments and cannot estimate the impact of adoption at this time.

#### **Comprehensive Income**

In June 2011, the FASB issued changes to the presentation of comprehensive income. These changes give an entity the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. The option to present components of other comprehensive income as part of the statement of changes in stockholders equity was eliminated. The items that must be reported in other comprehensive income were not changed. Additionally, no changes were made to the calculation and presentation of earnings per share. The amendment is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011 and is required to be applied retrospectively. We are currently evaluating these changes to determine which option will be chosen for the presentation of comprehensive income.

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

Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily a result of fluctuations in foreign currency exchange rates and interest rates. We do not hold or issue financial instruments for trading purposes.

#### Foreign Currency Exchange Risk

As we expand internationally our results of operations and cash flows will become increasingly subject to fluctuations due to changes in foreign currency exchange rates. Our revenue is generally denominated in the local currency of the contracting party. Historically, the substantial majority of our revenue has been denominated in U.S. dollars. Our expenses are generally denominated in the currencies in which our operations are located, which is primarily in the United States, with a portion of expenses incurred in Singapore where our manufacturing facility is located. Our results of operations and cash flows are, therefore, subject to fluctuations due to changes in foreign currency exchange rates. Fluctuations in currency exchange rates could harm our business in the future. The effect of a 10% adverse change in exchange rates on foreign currency denominated cash, receivables and payables as of December 31, 2011 and December 31, 2010 would not have been material. To date, we have not entered into any material foreign currency hedging contracts although we may do so in the future.

#### Interest Rate Sensitivity

We had cash and cash equivalents of \$13.6 million as December 31, 2011. These amounts were held primarily in cash on deposit with banks and money market funds, which are short-term. We had \$41.4 million in investments at December 31, 2011 held primarily in U.S. government agency securities with maturities of less than twelve months. Cash and cash equivalents are held for working capital purposes are held for working capital purposes. Due to the short-term nature of these investments, we believe that we do not have any material exposure to changes in the fair value of our investment portfolio as a result of changes in interest rates. Declines in interest rates, however, will reduce future investment income. If overall interest rates had decreased by 10% during the periods presented, our interest income would not have been materially affected.

As of December 31, 2011, the principal amount of our long-term debt outstanding was \$10.1 million and we had no outstanding balance on our bank line of credit. The interest rates on our long-term debt are fixed. If overall interest rates had increased by 10% during the periods presented, our interest expense would not have been materially affected.

#### Fair Value of Financial Instruments

We do not have material exposure to market risk with respect to investments. We do not use derivative financial instruments for speculative or trading purposes. We may adopt specific hedging strategies in the future.

# ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA Index to Consolidated Financial Statements

	Page
Report of Independent Registered Public Accounting Firm	70
Consolidated Balance Sheets	71
Consolidated Statements of Operations	72
Consolidated Statements of Convertible Preferred Stock and Stockholders _ Equity (Deficit)	73
Consolidated Statements of Cash Flows	76
Notes to Consolidated Financial Statements	77

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

The Board of Directors and Stockholders of

Fluidigm Corporation

We have audited the accompanying consolidated balance sheets of Fluidigm Corporation as of December 31, 2011 and 2010, and the related consolidated statements of operations, convertible preferred stock and stockholders equity (deficit), 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. These financial statements and 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. We were not engaged to perform an audit of the Company s internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and 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 Fluidigm Corporation 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.

/s/ Ernst & Young LLP

Redwood City, California

March 23, 2012

# FLUIDIGM CORPORATION

# CONSOLIDATED BALANCE SHEETS

# (In thousands, except per share amounts)

	December 31, 2011				December 31, 2010	
ASSETS						
Current assets:						
Cash and cash equivalents	\$	13,553	\$	5,723		
Short-term investments		39,914		0		
Accounts receivable (net of allowances of \$366 and \$467 at December 31, 2011 and 2010,						
respectively)		9,253		8,100		
Inventories		5,970		4,893		
Prepaid expenses and other current assets		1,343		2,165		
Total current assets		70.022		20.991		
		70,033		20,881		
Long-term investment		1,500		0		
Property and equipment, net		3,256		2,328		
Investment, at cost		1,340		1,340		
Other non-current assets		3,197		252		
Total assets	\$	79,326	\$	24,801		
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY						
(DEFICIT)						
Current liabilities:						
Accounts payable	\$	4,010	\$	3,155		
Accrued compensation and related benefits		2,442		1,904		

Accounts payable	\$ 4,01	0 \$	3,155
Accrued compensation and related benefits	2,44	2	1,904
Other accrued liabilities	2,78	7	3,379
Deferred revenue, current portion	2,01	1	1,336
Long-term debt, current portion	8,92	1	4,561
Line of credit		0	3,125
Convertible preferred stock warrants		0	1,052
Total current liabilities	20,17	1	18,512
Long-term debt, net of current portion	1,21	7	10,139
Deferred revenue, net of current portion	66	7	426
Other non-current liabilities	37-	4	341
Total liabilities	22,42	9	29,418
Commitments and contingencies			
Convertible preferred stock issuable in series: \$0.001 par value, 10,000 and 11,269 shares authorized at December 31, 2011 and 2010, respectively; 0 and 10,296 shares issued and			
outstanding at December 31, 2011 and 2010, respectively		0	184,550
Stockholders equity (deficit):			
Common stock: \$0.001 par value, 200,000 and 18,327 shares authorized at December 31, 2011 and 2010, respectively; 20,321 and 1,937 shares issued and outstanding at December 31, 2011 and 2010,			
respectively	2	0	2
Additional paid-in capital	279,42	•	10,936
Accumulated other comprehensive loss	(75-		(778)
Accumulated deficit	(221,79	,	(199,327)

Total stockholders equity (deficit)	56,897	(189,167)
Total liabilities, convertible preferred stock and stockholders equity (deficit)	\$ 79,326	\$ 24,801

# Edgar Filing: FLUIDIGM CORP - Form 10-K

See accompanying notes.

# FLUIDIGM CORPORATION

# CONSOLIDATED STATEMENTS OF OPERATIONS

# (In thousands, except per share amounts)

	Year-Ended December 31,		
	2011	2010	2009
Revenue:			
Product revenue	\$ 40,581	\$ 30,462	\$ 23,599
License and collaboration revenue	1,716	1,625	0
Grant revenue (includes grant revenue from related party of \$46, \$1,104 and \$1,522 for the			
years ended December 31, 2011, 2010, and 2009, respectively)	568	1,473	1,813
Total revenue	42,865	33,560	25,412
Costs and expenses:			
Cost of product revenue	13,191	11,581	11,486
Research and development	13,936	13,007	12,315
Selling, general and administrative	31,304	23,545	19,648
Litigation settlement	3,000	0	0
Total costs and expenses	61,431	48,133	43,449
Loss from operations	(18,566)	(14,573)	(18,037)
Interest expense (includes related party interest expense of \$44, \$0 and \$367 for the years			
ended December 31, 2011, 2010, and 2009, respectively)	(3,101)	(2,158)	(2,876)
Loss from changes in the fair value of convertible preferred stock			
warrants, net	(1,483)	(445)	(135)
Gain from extinguishment of convertible preferred stock warrants	765	0	0
Other income, net	81	357	1,870
Loss before income taxes	(22,304)	(16,819)	(19,178)
(Provision for) / benefit from income taxes	(166)	(83)	50
Net loss	(22,470)	(16,902)	(19,128)
Deemed dividend related to the change in conversion rate of Series E convertible preferred stock	(9,900)	0	0