GenMark Diagnostics, Inc.
Form 10-Q
May 13, 2011
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2011

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

For the transition period from _____ to _____

Commission File Number: 001-34753

Genmark Diagnostics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**27-2053069**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
5964 La Place Court, Suite 100, Carlsbad, California	**92008-8829**
(Address of principal executive offices)	**(Zip code)**

Registrant s telephone number, including area code: 760-448-4300

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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ¨ No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer x	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

The number of outstanding shares of the registrant s common stock on April 30, 2010 was 12,337,489.

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PART I- FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

GENMARK DIAGNOSTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

	As of March 31, 2011	As of December 31, 2010
Current assets		
Cash and cash equivalents	$ 17,054,095	$ 18,329,079
Accounts receivable, net	762,272	677,648
Inventories, net	871,033	896,809
Other current assets	382,194	2,193,160
Total current assets	19,069,594	22,096,696
Property and equipment, net	2,762,362	2,702,478
Intangible assets, net	68,042	70,980
Other long-term assets	55,355	55,355
Total assets	$ 21,955,353	$ 24,925,509
Current liabilities		
Accounts payable	$ 1,651,985	$ 823,242
Accrued compensation	1,019,545	1,171,989
Other current liabilities	1,761,011	1,249,928
Total current liabilities	4,432,541	3,245,159
Long-term liabilities		
Loan payable	2,000,000	
Other non-current liabilities	622,644	612,932
Total liabilities	$ 7,055,185	$ 3,858,091
Stockholders equity		
Common stock, $.0001 par value; 100,000,000 authorized; 11,738,233 and 11,723,512 issued and outstanding as of March 31, 2011 and December 31, 2010, respectively	1,172	1,172
Preferred stock, $0.0001 par value; 5,000,000 authorized, none issued		
Additional paid-in capital	166,483,672	166,009,084
Accumulated deficit	(151,134,719)	(144,492,881)
Accumulated other comprehensive loss	(449,957)	(449,957)
Total stockholders equity	14,900,168	21,067,418
Total liabilities and stockholders equity	$ 21,955,353	$ 24,925,509

See accompanying notes to unaudited condensed consolidated financial statements.

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GENMARK DIAGNOSTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended March 31,	
	2011	**2010**
Product Revenue	$ 692,739	$ 384,249
License and other revenue	71,664	15,015
Total revenue	764,403	399,264
Cost of sales	1,643,456	567,396
Gross loss	(879,053)	(168,132)
Operating expenses		
Sales and marketing	1,130,389	1,058,285
General and administrative	2,111,336	2,167,264
Research and development	2,528,252	1,453,759
Total operating expenses	5,769,977	4,679,308
Loss from operations	(6,649,030)	(4,847,440)
Other income		
Other income (expense)	11,899	(1,110)
Interest income	6,258	4,654
Total other income	18,157	3,544
Loss before income taxes	(6,630,873)	(4,843,896)
Provision for income taxes	(10,968)	(5,049)
Net loss	$ (6,641,841)	$ (4,848,945)
Net loss per share, basic and diluted	$ (0.56)	$ (0.68)
Weighted average number of shares outstanding	11,771,014	7,113,922
Condensed consolidated statements of comprehensive loss three and three months ended March 31, 2011 and 2010		
Net loss	$ (6,641,841)	$ (4,848,945)
Foreign currency translation adjustment		(34,647)
Comprehensive loss	$ (6,641,841)	$ (4,883,592)

See accompanying notes to unaudited condensed consolidated financial statements.

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GENMARK DIAGNOSTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Three Months Ended March 31,	
	2011	**2010**
Cash flows from operating activities:		
Net loss	$ (6,641,841)	$ (4,848,945)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	288,771	318,369
Change in allowance for doubtful accounts, net of write-offs	(47,785)	
Change in allowance for excess and obsolete inventory	(546)	
Share-based compensation	474,588	347,530
Changes in operating assets and liabilities:		
Trade accounts receivable	(36,839)	(71,316)
Inventories	26,322	(65,138)
Other current assets	1,810,966	(469,561)
Accounts payable	667,559	(316,564)
Accrued compensation	(152,444)	279,184
Accrued and other liabilities	520,798	(155,724)
Net cash used in operating activities	(3,090,451)	(4,982,165)
Investing activities:		
Purchases of property and equipment	(184,533)	(137,440)
Net cash used in investing activities	(184,533)	(137,440)
Financing activities:		
Proceeds of loan payable	2,000,000	
Proceeds from stock option exercises		4,734
Net cash provided by financing activities	2,000,000	4,734
Effect of foreign exchange rate changes		(46,935)
Net decrease in cash and cash equivalents	(1,274,984)	(5,114,871)
Cash and cash equivalents at beginning of period	18,329,079	16,482,818
Cash and cash equivalents at end of period	$ 17,054,095	$ 11,321,012
Noncash investing and financing activities:		
Reclassification of deposits on systems in other current assets		$ 285,284
IPO costs incurred but not paid included in accounts payable		1,537,192
Property and equipment costs incurred but not paid included in accounts payable	$ 161,184	

See accompanying notes to unaudited condensed consolidated financial statements.

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Genmark Diagnostics, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

1. Organization and basis of presentation

Genmark Diagnostics, Inc. (the Company or GenMark) is a molecular diagnostics company focused on developing and commercializing the Company s proprietary e-sensor technology. On February 12, 2010, the Company was established to serve as the parent company of Osmetech plc (Osmetech) upon a corporate reorganization and initial public offering (IPO). On June 3, 2010, the Company completed an IPO for 4,600,000 shares. Immediately prior to the completion of the IPO, the Company underwent a corporate reorganization whereby the ordinary shares of Osmetech were exchanged by its shareholders for the common stock of the Company on a 230 for 1 basis.

As the reorganization is deemed to be a transaction under common control, GenMark accounted for the reorganization in a manner similar to a pooling-of-interests, meaning:

(i) assets and liabilities were carried over at their respective carrying values;

(ii) common stock was carried over at the nominal value of the shares issued by GenMark;

(iii) additional paid-in capital represents the difference between the nominal value of the shares issued by GenMark, and the total of the additional paid-in capital and nominal value of Osmetech s shares cancelled pursuant to the described reorganization; and

(iv) the accumulated deficit represents the aggregate of the accumulated deficit of Osmetech and the Company.

Once the reorganization became effective, all stock options granted under the Osmetech plc 2003 U.S. Equity Compensation Plan, Long Term Incentive Awards and all warrants issued were exchanged for options and warrants exercisable for the common stock of the Company.

The preferred stock may be issued from time to time in one or more series.

In these consolidated financial statements, the Company means Osmetech when referring to periods prior to the corporate reorganization and IPO.

The Company evaluated subsequent events through May 13, 2011, being the date of issuance of the unaudited condensed consolidated financial statements.

The accompanying financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred net losses from operations since its inception and has an accumulated deficit of $151,134,719 at March 31, 2011. Cash and cash equivalents at March 31, 2011 were $17,054,095.

Management expects operating losses to continue through the foreseeable future until the Company has expanded its product offerings and increased its product revenues to an extent covers the fixed cost base of the business. The Company s management has prepared cash flow forecasts which indicate, based on the current cash resources available and the availability of unutilized credit facilities, that the Company has sufficient capital to fund its operations for at least the next twelve months.

The Company has prepared the accompanying unaudited condensed consolidated financial statements in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP) for interim financial information and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by U.S. GAAP for audited financial statements. In the opinion of management, all adjustments, which include only normal recurring adjustments considered necessary for a fair presentation, have been included. Operating results for the three months ended March 31, 2011 are not necessarily indicative of the results that may be expected for the year ending December 31, 2011. The information presented in the condensed consolidated financial statements and related footnotes at March 31, 2011, and for the three months ended March 31, 2011 and 2010, is unaudited and the condensed consolidated balance sheet amounts and related footnotes at December 31, 2010 have been derived from our audited financial statements. For further information, refer to the consolidated financial statements and accompanying footnotes included in our annual report Form 10-K filed with the Securities and Exchange Commission (SEC) on March 14, 2011.

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Genmark Diagnostics, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

The Company operates in one reportable segment, and substantially all of the Company s operations and assets are in the United States of America.

Principles of Consolidation-The unaudited condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (FASB) or other standard setting bodies that are adopted by the Company as of the specified effective date. We believe that the impact of recently issued standards that are not yet effective will not have a material impact on our financial position or results of operations upon adoption.

Fair Value of Financial Instruments

The Company s financial instruments consist of cash equivalents, accounts receivable, accounts payable and loan payable. The carrying amounts of accounts receivable, accounts payable and the loan payable are considered reasonable estimates of their fair value, due to the short maturity of these instruments. There were no significant financial instruments requiring one-time or recurring measurements of fair value during the three months ended March 31, 2011.

Accounting literature provides a fair value hierarchy, which classifies fair value measurements based on the inputs used in measuring fair value. These inputs include: Level 1, defined as observable inputs such as quoted prices for identical instruments in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs for which little or no market data exists, therefore requiring an entity to develop its own assumptions. There were no transfers of items between Levels 1, 2 or 3.

Cash and cash equivalents: The carrying amounts reported in the balance sheets for cash and cash equivalents are stated at their fair market value. Cash and cash equivalents are classified as Level 1.

Loan payable: The carrying amount reported in the balance sheets for the loan payable is considered a reasonable estimate of fair value, based on the short maturity and comparable terms for similar credit facilities. The loan payable is classified as Level 2.

Non-recurring measurements: The Company measures the fair value of its long-lived assets on a periodic basis when it appears that there may be requirement to do so, such as an indication of impairment. There was no impairment recorded for the three months ended March 31, 2011.

Income Taxes

Current income tax expense is the amount of income taxes expected to be payable for the current year. A deferred income tax liability or asset is established for the expected future tax consequences resulting from the differences in financial reporting and tax bases of assets and liabilities. A valuation allowance is provided if it is more likely than not that some or all of the deferred tax assets will not be realized. A full valuation allowance has been recorded against the Company s deferred tax assets due to the uncertainty surrounding the Company s ability to utilize these assets in the future. The Company provides for uncertain tax positions when such tax positions do not meet the recognition thresholds or measurement standards prescribed by the authoritative guidance on income taxes. Amounts for uncertain tax positions are adjusted in periods when new information becomes available or when positions are effectively settled. The Company recognizes accrued interest and penalties related to uncertain tax positions as a component of income tax expense.

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Genmark Diagnostics, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

2. Share-Based Compensation

The Company recognizes share-based compensation expense related to share options, warrants and restricted stock issued to employees, directors and consultants in exchange for services. The compensation expense is based on the fair value of the awards, which are determined by utilizing various assumptions regarding the underlying attributes of the options and shares. The estimated fair value of options granted and restricted stock, net of forfeitures expected to occur during the vesting period, is amortized as compensation expense on a straight line basis over the period the vesting occurs. The share-based compensation expense is recorded in cost of sales, sales and marketing, research and development and general and administrative expenses based on the employee s or consultant s respective function. The option and warrant-related expense is derived from the Black-Scholes Option Pricing Model that uses several judgment based variables to calculate the expense. The inputs include the expected life of the option or warrant, the expected volatility and other factors. The compensation expense related to the restricted stock is calculated as the difference between the fair market value of the stock on the date of grant, less the cost to acquire the shares, which is $0.0001 per share.

On June 3, 2010, the Company exchanged all of the outstanding options under the Osmetech plc 2003 U.S. Equity Compensation Plan (the U.S. Plan) for options under the 2010 Equity Incentive Plan (the Plan). The options were exchanged using an exchange ratio of 230 options to purchase shares of Osmetech plc to one share of the Company and was accounted for as a modification of the share-based payment arrangement. There was no additional compensation cost recorded related to the exchange as there was no change in the economic value of the options exchanged.

Employee participation in the Plan is at the discretion of the compensation committee or senior management of the Company. All options granted since June 3, 2010 are exercisable at a price equal to the average closing quoted market price of the Company s shares on the NASDAQ on the date of grant. Options granted prior to June 3, 2010 under the Osmetech plc 2003 U.S. Equity Compensation Plan were exercisable at a price equal to the average closing quoted market price of the Osmetech plc s shares on the Alternative Investment Market of the London Stock Exchange on the date of the grant as adjusted for the exchange ratio to the Company s shares as described above. Options generally vest between 1 and 4 years.

Options are generally exercisable for a period up to 10 years after grant and are forfeited if the employee leaves the Company before the options vest. As of March 31, 2011, 701,957 shares remained available for future grant of awards under the Plan. Restricted stock grants reduce the amount of stock options available for grant under the 2010 Plan and are excluded from the table below.

The following table summarizes stock option activity during the three months ended March 31, 2011:

	Number of Share options	Weighted average exercise price
Outstanding at December 31, 2010	1,107,920	$ 6.40
Granted	226,500	4.37
Exercised		
Cancelled	(19,445)	(0.37)
Outstanding at March 31, 2011	1,314,975	$ 6.06
Exercisable at March 31, 2011	516,596	$ 7.12

As of March 31, 2011, there were 1,314,975 options that are vested or expected to vest and these options have a remaining weighted average contractual term of 8.63 years, and an aggregate intrinsic value of $0.

During the three months ended March 31, 2011, the Company granted 130,800 shares of restricted stock to senior management employees and 10,000 shares of restricted stock to an outside consultant. The restricted stock granted to senior management employees vests over a four year period except for 4,000 shares of restricted stock issued to one employee as part of a separation agreement that vests May 31, 2011. The

restricted stock granted to the outside consultant vested on March 1, 2011 commensurate with the period of service rendered to the Company.

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Genmark Diagnostics, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

Valuation of Share-Based Awards The Black-Scholes option pricing model was used for estimating the grant date fair value of stock options granted during the three months ended March 31, 2011 with the following assumptions:

Expected volatility (%)	70.0
Expected life (years)	6.08
Risk free rate (%)	2.51
Expected dividend yield (%)	0

3. Net Loss Per Common Share

Basic net loss per share is computed by dividing loss available to common shareholders (the numerator) by the weighted average number of common shares outstanding during the period (the denominator). Shares issued during the period and shares reacquired during the period are weighted for the portion of the period that they were outstanding. Diluted loss per share is calculated in a similar way to basic loss per share except that the denominator is increased to include the number of additional shares that would have been outstanding if the dilutive potential shares had been issued unless the effect would be anti-dilutive. As the Company had a net loss in each of the periods presented, basic and diluted net loss per ordinary share are the same.

The computations of diluted net loss per share did not include the effects of the following securities as the inclusion of these items would have been anti-dilutive:

	Three months ended March 31,	
	2011	2010
Share options	1,314,975	960,624
Warrants	88,317	88,317
Restricted Stock vested; not issued or outstanding	61,057	
	1,464,349	1,048,941

Common Stock Warrants During 2009, the Company issued warrants to purchase 132,475 of Osmetech s ordinary shares with an exercise price of £4.60 per share, and warrants to purchase 88,317 of Osmetech s ordinary shares with an exercise price of £6.90 per share to a director for services to the Company in connection with the share offering completed in 2009. Pursuant to the terms of the warrant, the warrant to purchase 132,475 was cancelled upon the closing of the IPO in June 2010. At the same time, the warrant to purchase 88,317 of Osmetech s ordinary shares was converted to warrants to purchase 88,317 shares of the Company s common stock at an exercise price of $9.98. These warrants were fully vested and exercisable upon issue, and shall continue to be exercisable up to and including the earlier to occur of (i) 60 days after the director leaving the Company s board of directors (for whatever reason) and (ii) June 30, 2012.

4. Property and Equipment, net

Property and equipment was comprised of the following as of March 31, 2011 and December 31, 2010:

	March 31, 2011	December 31, 2010
Property and equipment at cost:		
Plant and machinery	$ 2,473,579	$ 2,451,775
Rental systems	3,125,399	2,821,665
Office equipment	1,548,235	1,541,544
Leasehold improvements	611,021	597,523
Total property and equipment at cost	7,758,234	7,412,506
Less accumulated depreciation	(4,995,872)	(4,710,029)
Net property and equipment	$ 2,762,362	$ 2,702,478

Depreciation expense amounted to $285,833 and $198,687 for the three months ended March 31, 2011 and 2010, respectively.

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Genmark Diagnostics, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

5. Loan payable

In March 2010, the Company entered into a loan and security agreement with Square 1 Bank, pursuant to obtaining a credit facility consisting of a revolving line of credit in the amount of up to $2 million and an equipment term loan in the amount of up to $2 million. Based upon certain financial covenants, interest on the revolving line of credit will be either (i) the greater of (a) the bank s prime rate (3.25% as of March 31, 2011) plus 2.75%, or (b) 6%; or (ii) the greater of (a) the bank s prime rate plus 3.75%, or (b) 7%. In addition, based upon certain financial covenants, interest on the equipment term loan will be either (i) the greater of (a) the bank s prime rate plus 3.25%, or (b) 6.50%; or (ii) the greater of (a) the bank s prime rate plus 4.25%, or (b) 7.50%. The revolving line matures in July 2011 and the term loan matures in July 2013. In March 2011, the loan and security agreement was amended, whereby the line of credit availability was increased to $3 million and the maturity was extended to July 2012. The term loan was modified to allow invoices up to 360 days to qualify to be submitted for credit extension. There were no other changes to these two loans.

In March 2011, an additional loan was made available under the amended loan and security agreement for up to $1.0 million to finance equipment purchases. Based upon certain financial covenants, interest on this equipment term loan will be either (i) the greater of (a) the bank s prime rate plus 3.25%, or (b) 6.50%; or (ii) the greater of (a) the bank s prime rate plus 4.25%, or (b) 7.50%. This term loan matures March 2014.

As of March 31, 2011, the Company had no outstanding loans on the line of credit or the 2011 equipment loan and had drawn $2.0 million to finance 2010 equipment purchases and tenant improvements to its Carlsbad facility against the original 2010 equipment term loan. The loan bears an interest rate of 6.5%.

Pursuant to the terms of the loan and security agreement, we are required to maintain a ratio of liquidity to bank indebtedness equal to at least 1.50 to 1.00. In addition, the loan and security agreement includes several restrictive covenants, including requirements that we obtain the consent of Square 1 Bank prior to entering into any change of control event unless all debt is repaid to Square 1 Bank prior to the change of control event, incurring other indebtedness or liens with respect to our property, making distributions to our stockholders, making certain investments or entering into certain transactions with affiliates and other restrictions on storing inventory and equipment with third parties. The agreement also limits the amount we can borrow under the term loan to license genetic biomarkers to $500,000. To secure the credit facility, we granted Square 1 Bank a first priority security interest in our assets and intellectual property rights. We are currently in compliance will all ratios and covenants.

6. Income taxes

The Company uses an estimated annual effective tax rate, which is based on expected annual income, statutory tax rates and tax planning opportunities available in the various jurisdictions in which the Company operates, to determine its quarterly provision for income taxes. Certain significant or unusual items are separately recognized in the quarter in which they occur and can be a source of variability in the effective tax rates from quarter to quarter.

As of March 31, 2011, the Company has recorded a full valuation allowance against its deferred tax assets due to the uncertainty surrounding the Company s ability to utilize these assets in the future. Provision for income tax was $11,000 and $5,000 for the three months ended March 31, 2011 and 2010, respectively. Due to the Company s losses it only records tax provision or benefit related to minimum tax payments or refunds and interest and penalties related to its uncertain tax positions.

The total amount of unrecognized tax benefits was $382,000 as of March 31, 2011 which would impact the effective tax rate if recognized. The gross liability for income taxes related to unrecognized tax benefits is included in other long-term liabilities in the Company s condensed consolidated balance sheets.

The total balance of accrued interest related to uncertain tax positions was $104,770 as of March 31, 2011. The Company recognizes interest and penalties related to uncertain tax positions as a component of income tax expense. The Company does not expect its unrecognized tax benefits to change significantly over the next twelve months.

The Company is subject to taxation in the U.S., UK based on its legacy operations, and in various state jurisdictions. As of March 31, 2011 the Company s tax years after 2007 are subject to examination by the UK tax authorities. Except for net operating losses generated in prior years carrying forward to the current year, as of March 31, 2011, the Company is no longer subject to U.S. federal, state, local or foreign examinations by tax authorities for years before 2006.

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ITEM 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion of our financial condition and results of operations should be read with our unaudited condensed consolidated financial statements and notes included in Item 1 of this Quarterly Report for the three months ended March 31, 2011, as well as the audited financial statements and notes and Management s Discussion and Analysis of Financial Condition and Results of Operations for the fiscal year ended December 31, 2010, included in our annual report Form 10-K dated March 11, 2011 filed with the SEC. This Management s Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements regarding future events and our future results are based on current expectations, estimates, forecasts, and projections and the beliefs and assumptions of our management including, without limitation, our expectations regarding our results of operations, sales and marketing expenses, general and administrative expenses, research and development expenses, and the sufficiency of our cash for future operations. Words such as we expect, anticipate, target, project, believe, goals, estimate, potential, may, will, expect, might, could, intend, variations of these terms or the negative of those terms and similar expressions are intended to ide these forward-looking statements. Readers are cautioned that these forward-looking statements are predictions and are subject to risks, uncertainties, and assumptions that are difficult to predict. Therefore, actual results may differ materially and adversely from those expressed in any forward-looking statements.

Among the important factors that could cause actual results to differ materially from those indicated by our forward-looking statements are those discussed under the heading Risk Factors in Item 1A of Part I of our Annual Report on Form 10-K for the year ended December 31, 2010 and any risk factors described under the heading Risk Factors in Item 1A of Part II of this Quarterly Report. We do not intend to update these forward looking statements to reflect future events or circumstances.

Overview

GenMark Diagnostics, Inc., or GenMark, was formed by Osmetech plc, or Osmetech, in Delaware in February 2010 and had no operations prior to its initial public offering which was completed in June 2010. Immediately prior to the closing of the initial public offering, GenMark acquired all of the outstanding ordinary shares of Osmetech in a reorganization under the applicable laws of the United Kingdom. As a result of the reorganization, all of the issued ordinary shares in Osmetech were cancelled in consideration of (i) the issuance of common stock of GenMark to the former shareholders of Osmetech and (ii) the issuance of new shares in Osmetech to GenMark. Following the reorganization, Osmetech became a subsidiary controlled by GenMark, and the former shareholders of Osmetech began to hold shares of GenMark. Any historical discussion of GenMark relates to Osmetech and its consolidated subsidiaries prior to the reorganization.

We are a molecular diagnostics company focused on developing and commercializing our proprietary eSensor detection technology. Our proprietary electrochemical technology enables fast, accurate and highly sensitive detection of up to 72 distinct biomarkers in a single sample. Our XT-8 system received 510(k) clearance from the Food and Drug Administration, or FDA, and is designed to support a broad range of molecular diagnostic tests with a compact and easy-to-use workstation and self-contained, disposable test cartridges. Within 30 minutes of receipt of an amplified DNA sample, our XT-8 system produces clear and accurate results. Our XT-8 system supports up to 24 independent test cartridges, which can be run independently, resulting in a highly convenient and flexible workflow for our target customers, which are hospitals and reference laboratories.

We have developed four diagnostic tests for use with our XT-8 system and expect to expand this test menu by introducing two to four new tests annually. Our Cystic Fibrosis Genotyping Test, which detects pre-conception risks of cystic fibrosis, our Warfarin Sensitivity Test, which determines an individual s ability to metabolize the oral anticoagulant warfarin, and our Thrombophilia Risk Test, which detects an individual s increased risk of blood clots, have received FDA clearance. Our eSensor technology has demonstrated 100% accuracy in clinical studies compared to DNA sequencing in our Cystic Fibrosis Genotyping Test, our Warfarin Sensitivity Test and our Thrombophilia Risk Test. We have also developed a Respiratory Viral Panel Test, which detects the presence of major respiratory viruses and is labeled for investigational use only, or IUO. We intend to seek FDA clearance for our Respiratory Viral Panel Test in 2011. We also have a pipeline of several additional potential products in different stages of development or design, including diagnostic tests for an individual s sensitivity to Plavix, a commonly prescribed anti-coagulant, and for mutations in a gene known as K-ras, which is predictive of an individual s response rates to certain prescribed anti-cancer therapies.

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We are also developing our next-generation platform, the NexGen system. We are designing the NexGen system to integrate DNA amplification with our eSensor detection technology to enable technicians using the NexGen system to be able to place a raw or minimally prepared patient sample into our test cartridge and obtain results without any additional steps. This sample to answer capability is enabled by the robust nature of our eSensor detection technology, which is not impaired by sample impurities that we believe hinder competing technologies. We are designing our NexGen system to further simplify workflow and provide powerful, cost-effective molecular diagnostics solutions to a significantly expanded group of hospitals and reference laboratories.

Since inception, we have incurred net losses from continuing operations each year, and we expect to continue to incur losses for the foreseeable future. Our losses attributable to continuing operations for the three months ended March 31, 2011 and 2010 were approximately $6.6 million and $4.8 million, respectively. As of March 31, 2011, we had an accumulated deficit of $151.1 million. Our operations to date have been funded principally through sales of capital stock and sales of our previous businesses. We expect to incur increasing expenses over the next several years, principally to develop additional diagnostic tests, as well as to further increase our spending to manufacture, sell and market our products.

Results of Operations Three months ended March 31, 2011 compared to the three months ended March 31, 2010

Revenue

	March 31,			
	2011	**2010**	**$ Change**	**% Change**
Three months ended	$ 764,403	$ 399,264	$ 365,139	91%

The increase in revenue for the three month period ended March 31, 2011 as compared to the three month period ended March 31, 2010 was primarily due to a $331,000 increase in reagent revenue driven by the increase in number of our installed base of systems as well as an expanded menu of tests available for sale.

Cost of Sales and Gross Loss

	March 31,			
	2011	**2010**	**$ Change**	**% Change**
Cost of Sales-three months ended	$ 1,643,456	$ 567,396	$ 1,076,060	190%
Gross Loss -three months ended	$ 879,053	$ 168,132	$ 710,921	423%

The increase in cost of sales for the three months ended March 31, 2011 compared to the three months ended March 31, 2010 was due to $605,000 in increased expenses related directly to the increase in reagent and system shipments, as well as costs incurred in relocating our manufacturing facilities from Pasadena to our Carlsbad location in 2011, including $314,000 in higher payroll, benefits and temporary labor costs and $188,000 of additional facility-related charges. The increase in gross loss resulted primarily from costs associated with our expanded product offerings which will be reduced as a percentage of sales as our sales volume increases, and the one-time expense of relocating our manufacturing facility which should be completed by the end of the second quarter of 2011.

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Operating Expenses

Sales and Marketing

	March 31,			
	2011	2010	$ Change	% Change
Three months ended	$ 1,130,389	$ 1,058,285	$ 72,104	7%

The increase in sales and marketing expense was driven primarily by increased costs for product samples sent to prospective customers.

General and Administrative

	March 31,			
	2011	2010	$ Change	% Change
Three months ended	$ 2,111,336	$ 2,167,264	$ (55,928)	(3)%

General and administrative expense decreased for the three months ended March 31, 2011 compared to the three months ended March 31, 2010 due to $925,000 in lower payroll, severance and other headcount related costs associated with our former UK operations and lower facility-related costs. These reductions were offset by a $370,000 increase in professional services fees primarily related to corporate restructuring, and $550,000 in additional consulting, share-based compensation and recruiting costs for executive services.

Research and Development

	March 31,			
	2011	2010	$ Change	% Change
Three months ended	$ 2,528,252	$ 1,453,759	$ 1,074,493	74%

The increase in research and development expense for the three months ended March 31, 2011 was due to $150,000 in higher payroll expense due to increased headcount, severance related expenses of $239,000, increased development supplies and clinical trial costs of $160,000, a $133,000 increase in intellectual property related costs, costs of $250,000 incurred to obtain regulatory certification for our Carlsbad manufacturing facility and $117,000 of increased facility related costs in 2011 as compared to the same period in 2010.

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Other Income, Net

	March 31,			
	2011	2010	$ Change	% Change
Three months ended	$ 18,157	$ 3,544	$ 14,613	412%

Interest and other income (expense) represent earnings on cash and cash equivalents and foreign currency gains or losses. The increase in revenue for the three months ended March 31, 2011 as compared to the same period in 2010 was due primarily to a foreign currency gain related to accounts receivable from the UK in 2010 that was received in 2011 at higher foreign currency translation rates. During the second quarter of 2010, the Company shut down its UK facility and changed its functional currency to the U.S. dollar. There are no remaining material operations in the UK.

Provision for Income Taxes

	March 31,			
	2010	2009	$ Change	% Change
Three months ended	$ 10,968	$ 5,049	$ 5,919	117%

Due to the Company s losses it has only recorded tax provisions or benefits related to interest on uncertain tax positions, minimum tax payments and refunds.

Liquidity and Capital Resources

To date we have funded our operations primarily from the sale of our common stock and revenues. We have incurred net losses from continuing operations each year and have not yet achieved profitability. At March 31, 2011, we had $14.7 million of working capital, including $17.1 million in cash and cash equivalents.

Cash Flows

The following table summarizes, for the periods indicated, selected items in our consolidated statements of cash flows:

	March 31,	
	2011	2010
Three months ended:		
Cash used by operating activities	$ (3,090,451)	$ (4,982,165)
Cash used by investing activities	(184,533)	(137,440)
Cash provided by financing activities	2,000,000	4,734
Decrease in cash and cash equivalents	$ (1,274,984)	$ (5,114,871)

Cash flows used by operating activities

Net cash used in operating activities decreased $1.9 million to $3.1 million for the three months ended March 31, 2011 compared to $5.0 million for the three months ended March 31, 2010. The decreased use of cash was due primarily to collection of a $1.6 million therapeutic tax credit and $1.2 million of higher accounts payable and accrued liabilities in the current quarter, partially offset by accrued IPO costs at March 31, 2010 that were subsequently paid in 2010.

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Cash flows used by investing activities

Net cash used in investing activities increased $48,000 to $185,000 for the three months ended March 31, 2011 compared to $137,000 for the three months ended March 31, 2010 primarily due to increased purchases of our XT-8 systems used for customer rentals which are included in property and equipment.

Cash flows provided by financing activities

Net cash provided by financing activities increased by $2.0 million for the three months ended March 31, 2011 compared to the three months ended March 31, 2010 resulting from proceeds of a loan payable drawn in March 2011 to finance equipment purchases and tenant improvements purchased in 2010.

In March 2010, we entered into a loan and security agreement with Square 1 Bank, pursuant to which we obtained a credit facility consisting of a revolving line of credit in the amount of up to $2 million and an equipment term loan in the amount of up to $2 million. Based upon certain financial covenants, interest on the revolving line of credit will be either (i) the greater of (a) the bank s prime rate (3.25% as of March 31, 2011) plus 2.75%, or (b) 6%; or (ii) the greater of (a) the bank s prime rate plus 3.75%, or (b) 7%. In addition, based upon certain financial covenants, interest on the equipment term loan will be either (i) the greater of (a) the bank s prime rate plus 3.25%, or (b) 6.50%; or (ii) the greater of (a) the bank s prime rate plus 4.25%, or (b) 7.50%. The revolving line matures in July 2011 and the term loan matures in July 2013. In March 2011, the loan and security agreement was amended, whereby the line of credit availability was increased to $3 million and the maturity was extended to July 2012. The term loan was modified to allow invoices up to 360 days to qualify to be submitted for credit extension. There were no other changes to these two loans.

In March 2011, an additional loan was made available under the amended loan and security agreement for up to $1 million to finance equipment purchases. Based upon certain financial covenants, interest on this equipment term loan will be either (i) the greater of (a) the bank s prime rate plus 3.25%, or (b) 6.50%; or (ii) the greater of (a) the bank s prime rate plus 4.25%, or (b) 7.50%. This term loan matures March 2014.

As of March 31, 2011, the Company had no outstanding loans on the line of credit or the 2011 equipment loan and had drawn $2.0 million to finance 2010 equipment purchases and tenant improvements to its Carlsbad facility against the original 2010 equipment term loan. The loan bears an interest rate of 6.5%.

Pursuant to the terms of the loan and security agreement, we are required to maintain a ratio of liquidity to bank indebtedness equal to at least 1.50 to 1.00. In addition, the loan and security agreement includes several restrictive covenants, including requirements that we obtain the consent of Square 1 Bank prior to entering into any change of control event unless all debt is repaid to Square 1 Bank prior to the change of control event, incurring other indebtedness or liens with respect to our property, making distributions to our stockholders, making certain investments or entering into certain transactions with affiliates and other restrictions on storing inventory and equipment with third parties. The agreement also limits the amount we can borrow under the term loan to license genetic biomarkers to $500,000. To secure the credit facility, we granted Square 1 Bank a first priority security interest in our assets and intellectual property rights. We are currently in compliance will all ratios and covenants.

The Company s management has prepared cash flow forecasts which indicate, based on the current cash resources available, the availability of unutilized credit facilities, and our ability to access the equity markets will be sufficient to fund our business for at least the next 12 months. We expect capital outlays and operating expenditures to increase over the next several years as we grow our customer base and revenues, expand our research and development, commercialization and manufacturing activities. The amount of additional capital we may need to raise in the future depends on many factors, including:

- the level of revenues and the rate of revenue growth;
- the level of expenses required to expand our sales and marketing activities;

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the level of research and development investment required to maintain and improve our technology;

our need to acquire or license complementary technologies or acquire complementary businesses;

the costs of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;

competing technological and market developments; and

changes in regulatory policies or laws that affect our operations.

We cannot be certain that additional capital will be available when and as needed or that our actual cash requirements will not be greater than anticipated. If we require additional capital at a time when investment in diagnostics companies or in the marketplace in general is limited due to the then prevailing market or other conditions, we may not be able to raise such funds at the time that we desire, on acceptable terms, or at all. In addition, if we raise additional funds through the issuance of equity or convertible debt securities, the percentage ownership of our stockholders could be significantly diluted, and these newly issued securities may have rights, preferences or privileges senior to those of existing stockholders. If we obtain additional debt financing, a substantial portion of our operating cash flow may be dedicated to the payment of principal and interest on such indebtedness, and the terms of the debt securities issued could impose significant restrictions on our operations. If we raise additional funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies or products, or grant licenses on terms that are not favorable to us.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based upon our unaudited condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate our estimates including those related to bad debts, inventories, valuation of intangibles and other long-term assets, income taxes, and stock-based compensation. We base our estimates on historical experience and on various other assumptions we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities not readily apparent from other sources. Actual results may differ from these estimates. Our critical accounting policies and estimates are discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2010 and there have been no material changes during the three months ended March 31, 2011.

Contractual Obligations

On February 8, 2010, we entered into a seven-year and seven-month lease for a new 31,098 square foot facility in Carlsbad, California. The facility is part of a three-building office and research and development project located at 5964 La Place Court, Carlsbad, California, and the project totals 158,733 rentable square feet. Monthly rental payments of $45,092 commenced on July 14, 2010 and increase 3% annually thereafter. We also pay our pro-rata share of the building and project maintenance, property tax, management and other costs subject to certain limitations. We have paid a $55,000 security deposit and provided a $500,000 standby letter of credit as security for the future rent as well as for up to $2.0 million in landlord funded tenant improvements. The lease also provides for rights of first refusal for expansion within our building, subject to certain limitations.

On February 28, 2011, we entered into a 36 month operating lease for office equipment with total lease payments of $85,000. In conjunction with the lease, the lessor paid the Company approximately $27,000 to payoff previous contracts for similar equipment leased from a different vendor.

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Other Off-Balance Sheet Arrangements

We have no other off-balance sheet arrangements except for our unutilized credit facilities with Square 1 Bank that provides a revolving line of credit up to $2 million and an unutilized equipment term loan totalling $1 million at March 31, 2011.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk is limited to our cash and cash equivalents, all of which have maturities of less than three months. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. We also seek to maximize income from our investments without assuming significant risk. To achieve our goals, in the future we may maintain a portfolio of cash equivalents and investments in a variety of securities that management believes to be of high credit quality. We currently do not hedge interest rate exposure. Because of the short-term maturities of our cash equivalents, we do not believe that an increase in market rates would have a material negative impact on the value of our portfolio.

Interest Rate Risk

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio. The fair market value of fixed rate securities may be adversely impacted by fluctuations in interest rates while income earned on floating rate securities may decline as a result of decreases in interest rates. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We attempt to ensure the safety and preservation of our invested principal funds by limiting default risk, market risk and reinvestment risk. We mitigate default risk by investing in investment grade securities. We have historically maintained a relatively short average maturity for our investment portfolio, and we believe a hypothetical 10% adverse move in interest rates along the entire interest rate yield curve would not materially affect the fair value of our interest sensitive financial instruments.

Foreign Currency Exchange Risks

All of our operating facilities are located within the United States. We are a U.S. entity and our functional currency is the U.S. dollar. Virtually all of our revenues are based in the United States. A small portion of our expenses in the first quarter of 2010, relating to our corporate office, were transacted in British pounds. We currently have no material operations outside of the United States which diminishes the extent of any foreign currency exchange risk.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended (Exchange Act), is recorded, processed, summarized and reported within the timelines specified in the SEC s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance management necessarily is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we carried out an evaluation of the effectiveness of the Company s disclosure controls and procedures (as such term is defined in Exchange Act Rules 13a 15(e) and 15d 15(e)) as of March 31, 2011. Based on such evaluation, our management has concluded that as of March 31, 2011, the Company s disclosure controls and procedures are effective.

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Changes in Internal Control over Financial Reporting

As required by Rule 13a-15(d) of the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation of the internal control over financial reporting to determine whether any changes occurred during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Based on that evaluation, our principal executive officer and principal financial officer concluded no such changes during the period covered by this Quarterly Report on Form 10-Q materially affected, or were reasonably likely to materially affect, our internal control over financial reporting.

PART II-OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are from time to time subject to various claims and legal actions during the ordinary course of our business. We believe that there are currently no claims or legal actions that would reasonably be expected to have a material adverse effect on our results of operations or financial condition.

ITEM 1A. RISK FACTORS

An investment in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described under Item 1A of Part I of our Annual Report on Form 10-K filed with the Securities and Exchange Commission for the year ended December 31, 2010 (the Risk Factors), together with all other information contained or incorporated by reference in this report before you decide to invest in our common stock. If any of the risks described in this report or in our Annual Report on Form 10-K actually occurs, our business, financial condition, results of operations and our future growth prospects could be materially and adversely affected. Under these circumstances, the trading price of our common stock could decline, and you may lose all or part of your investment. There have been no material changes to the Risk Factors since the filing of our Annual Report.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Unregistered Sales of Equity Securities

None

Use of Proceeds from Registered Securities

On June 3, 2010, we closed our initial public offering, in which we sold 4,600,000 shares of common stock at a price to the public of $6.00 per share. The aggregate offering price for shares sold in the offering was $27.6 million. The offer and sale of all of the shares in the initial public offering were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-165562), which was declared effective by the SEC on May 28, 2010. The offering commenced as of May 28, 2010 and did not terminate before all of the securities registered in the registration statement were sold. Piper Jaffray acted as sole book-running manager for the offering. William Blair & Company and ThinkEquity LLC acted as co-managers of the offering. There were no selling stockholders in the offering. We raised approximately $22.6 million in net proceeds after deducting underwriting discounts and commissions of $1.9 million and other offering expenses of $3.0 million. No payments were made by us to directors, officers or persons owning ten percent or more of our common stock or to their associates, or to our affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors as compensation for board or board committee service. There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the SEC on June 1, 2010 pursuant to Rule 424(b). We invested the funds received in registered money market funds.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

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ITEM 4. (REMOVED AND RESERVED).

ITEM 5. OTHER INFORMATION.

None.

ITEM 6. EXHIBITS.

The exhibits listed in the Exhibit Index are incorporated herein by reference.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

GENMARK DIAGNOSTICS, INC.

Date: May 13, 2011

/s/ Paul Ross
Paul Ross
Chief Financial Officer
(principal financial and accounting officer)

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EXHIBIT INDEX

Listed and indexed below are all Exhibits filed as part of this report.

10.30#	Separation Agreement and General Release dated March 24, 2011, by and between Clinical Micro Sensors, Inc. d.b.a. GenMark Diagnostics, Inc. and Pankaj Singhal (incorporated by reference to Exhibit 10.1 on our Form 8-K filed with the Commission on March 28, 2010).
10.31#	Employee Offer Letter, dated March 11, 2011, by and between Clinical Micro Sensors, Inc. d.b.a. GenMark Diagnostics, Inc. and Paul Ross (incorporated by reference to Exhibit 10.1 on our Form 8-K/A filed with the Commission on April 7, 2011).
10.32#	Executive Employment Agreement dated March 1, 2010, by and between Clinical Micro Sensors, Inc. d.b.a. GenMark Diagnostics, Inc. and Jeffrey Hawkins.
10.33#	Executive Consulting Agreement dated October 12, 2010, by and between Clinical Micro Sensors, Inc. d.b.a. GenMark Diagnostics, Inc. and Kuranda Partners, LLC.
10.34#	Executive Employment Agreement, dated April 5, 2011, by and between GenMark Diagnostics, Inc. and Hany Massarany.
31.1	Certification of Principal Executive Officer Required Under Rule13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended
31.2	Certification of Principal Financial Officer Required Under Rule13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350.

# Indicates management contract or compensatory plan.