

GEN PROBE INC
Form 10-Q
November 03, 2011
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the quarterly period ended September 30, 2011

OR

Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the transition period from _____ to _____

Commission File Number: 000-49834

GEN-PROBE INCORPORATED

(Exact Name of Registrant as Specified in Its Charter)

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Delaware
(State or other jurisdiction of
incorporation or organization)

33-0044608
(I.R.S. Employer
Identification Number)

10210 Genetic Center Drive,

San Diego, CA
(Address of Principal Executive Office)

92121-4362
(Zip Code)

(858) 410-8000

(Registrant's telephone number, including area code)

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 twelve 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 ninety days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T 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 the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer
Non-accelerated filer (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

As of October 31, 2011, 46,514,305 shares of the registrant's common stock, \$0.0001 par value per share, were outstanding.

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(In thousands, except share and per share data)

	September 30, 2011 (Unaudited)	December 31, 2010
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 142,079	\$ 59,690
Marketable securities	160,305	170,648
Trade accounts receivable, net of allowance for doubtful accounts of \$352 and \$355 at September 30, 2011 and December 31, 2010, respectively	55,956	54,739
Accounts receivable - other	2,243	5,493
Inventories	76,529	66,416
Deferred income tax	12,109	13,634
Prepaid income tax	375	2,993
Prepaid expenses	16,745	11,672
Other current assets	3,250	5,148
Total current assets	469,591	390,433
Marketable securities, net of current portion	123,946	259,317
Property, plant and equipment, net	170,306	160,863
Capitalized software, net	16,740	13,981
Patents, net	11,968	12,450
Goodwill	149,189	150,308
Purchased intangibles, net	113,110	120,270
License, manufacturing access fees and other assets, net	62,717	60,175
Total assets	\$ 1,117,567	\$ 1,167,797
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	\$ 12,034	\$ 14,614
Accrued salaries and employee benefits	24,668	26,825
Other accrued expenses	13,092	13,935
Income tax payable	4,486	634
Short-term borrowings	248,000	240,000
Deferred revenue	935	1,166
Total current liabilities	303,215	297,174
Non-current income tax payable	9,571	8,315
Deferred income tax	26,408	29,775
Deferred revenue, net of current portion	2,610	2,500
Other long-term liabilities	6,937	6,654
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.0001 par value per share; 20,000,000 shares authorized, none issued and outstanding		
Common stock, \$0.0001 par value per share; 200,000,000 shares authorized, 46,507,028 and 47,966,156 shares issued and outstanding at September 30, 2011 and December 31, 2010, respectively	5	5
Additional paid-in capital	111,106	195,820
Accumulated other comprehensive income	574	678
Retained earnings	657,141	626,876

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Total stockholders' equity	768,826	823,379
Total liabilities and stockholders' equity	\$ 1,117,567	\$ 1,167,797

See accompanying notes to consolidated financial statements

Table of Contents**GEN-PROBE INCORPORATED****CONSOLIDATED STATEMENTS OF INCOME**

(In thousands, except per share data)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Revenues:				
Product sales	\$ 136,393	\$ 128,313	\$ 407,426	\$ 391,616
Collaborative research revenue	1,128	3,405	6,313	10,810
Royalty and license revenue	1,602	847	4,320	4,207
Total revenues	139,123	132,565	418,059	406,633
Operating expenses:				
Cost of product sales (excluding acquisition-related intangible amortization)	40,529	42,146	121,903	129,118
Acquisition-related intangible amortization	2,767	2,201	8,301	6,616
Research and development	27,864	27,433	84,540	84,218
Marketing and sales	17,308	13,872	51,340	44,476
General and administrative	18,298	11,510	55,154	41,208
Total operating expenses	106,766	97,162	321,238	305,636
Income from operations	32,357	35,403	96,821	100,997
Other income (expense):				
Investment and interest income	3,706	3,197	7,378	10,364
Interest expense	(524)	(586)	(1,524)	(1,681)
Gain on contingent consideration		1,513		7,595
Other-than-temporary impairment loss on equity investment	(39,482)		(39,482)	
Other income (expense), net	(1,364)	267	128	(82)
Total other income (expense), net	(37,664)	4,391	(33,500)	16,196
Income (loss) before income tax	(5,307)	39,794	63,321	117,193
Income tax expense	10,049	12,398	33,056	37,494
Net income (loss)	\$ (15,356)	\$ 27,396	\$ 30,265	\$ 79,699
Net income (loss) per share:				
Basic	\$ (0.33)	\$ 0.57	\$ 0.63	\$ 1.63
Diluted	\$ (0.33)	\$ 0.56	\$ 0.62	\$ 1.61
Weighted average shares outstanding:				
Basic	47,092	48,254	47,613	48,796
Diluted	47,092	48,679	48,813	49,257

See accompanying notes to consolidated financial statements

Table of Contents**GEN-PROBE INCORPORATED****CONSOLIDATED STATEMENTS OF CASH FLOWS**

(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2011	2010
Operating activities:		
Net income	\$ 30,265	\$ 79,699
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	34,952	34,111
Amortization of premiums on investments, net of accretion of discounts	7,301	6,796
Stock-based compensation	19,226	18,538
Excess tax benefit from employee stock-based compensation	(4,418)	(891)
Deferred revenue	(91)	(1,528)
Deferred income tax	(1,601)	(3,708)
Gain on contingent consideration		(7,595)
Other-than-temporary impairment loss on equity investment	39,482	
Loss on disposal of property and equipment	251	603
Changes in assets and liabilities:		
Trade and other accounts receivable	2,031	(2,127)
Inventories	(4,327)	204
Prepaid expenses	(5,072)	2,861
Other current assets	1,909	685
Other long-term assets	952	(353)
Accounts payable	(2,589)	(6,177)
Accrued salaries and employee benefits	(1,181)	(3,884)
Other accrued expenses	(873)	(2,230)
Income tax payable	11,303	10,863
Other long-term liabilities	300	(268)
Net cash provided by operating activities	127,820	125,599
Investing activities:		
Proceeds from sales and maturities of marketable securities	416,211	405,688
Purchases of marketable securities	(316,625)	(313,475)
Purchases of property, plant and equipment	(34,446)	(22,090)
Purchases of capitalized software	(5,032)	(2,081)
Purchases of intangible assets, including licenses and manufacturing access fees	(4,980)	(2,139)
Cash paid for investment in Pacific Biosciences		(50,000)
Cash paid for investment in Roka Bioscience	(3,980)	
Other	(225)	(83)
Net cash provided by investing activities	50,923	15,820
Financing activities:		
Repurchase and retirement of common stock	(150,000)	(88,079)
Proceeds from issuance of common stock and employee stock purchase plan	43,435	24,699
Payment of contingent consideration		(10,000)
Repurchase and retirement of restricted stock for payment of taxes	(1,614)	(1,252)

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Excess tax benefit from employee stock-based compensation	4,418	891
Borrowings, net	8,000	
Net cash used in financing activities	(95,761)	(73,741)
Effect of exchange rate changes on cash and cash equivalents	(593)	(1,234)
Net increase in cash and cash equivalents	82,389	66,444
Cash and cash equivalents at the beginning of period	59,690	82,616
Cash and cash equivalents at the end of period	\$ 142,079	\$ 149,060

See accompanying notes to consolidated financial statements

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Notes to the Consolidated Financial Statements (unaudited)

Note 1 Summary of Significant Accounting Policies

Basis of Presentation

The accompanying interim consolidated financial statements of Gen-Probe Incorporated (Gen-Probe or the Company) at September 30, 2011, and for the three and nine month periods ended September 30, 2011 and 2010, are unaudited and have been prepared in accordance with United States generally accepted accounting principles (U.S. GAAP) for interim financial information. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. In management s opinion, the unaudited interim consolidated financial statements include all adjustments, consisting only of normal recurring accruals, necessary to state fairly the financial information therein in accordance with U.S. GAAP. Interim results are not necessarily indicative of the results that may be reported for any other interim period or for the year ending December 31, 2011.

These unaudited interim consolidated financial statements and related footnotes should be read in conjunction with the audited consolidated financial statements and related footnotes contained in the Company s Annual Report on Form 10-K for the year ended December 31, 2010.

Certain prior year amounts have been reclassified to conform to the current year presentation. Such reclassifications did not affect total revenues, income from operations, or net income (loss).

Principles of Consolidation

These unaudited interim consolidated financial statements include the accounts of Gen-Probe as well as its wholly owned subsidiaries. All material intercompany transactions and balances have been eliminated in consolidation. The Company has not identified any interests in variable interest entities that require consolidation.

In December 2010, the Company acquired Genetic Testing Institute, Inc. (GTI Diagnostics), a privately held Wisconsin corporation now known as Gen-Probe GTI Diagnostics, Inc. GTI Diagnostics has broadened and strengthened the Company s transplant diagnostics business, and has also provided the Company with access to new products in the specialty coagulation and transfusion-related blood bank markets. GTI Diagnostics results of operations have been included in the Company s consolidated financial statements beginning in December 2010.

In October 2009, the Company acquired Prodesse, Inc. (Prodesse), a privately held Wisconsin corporation now known as Gen-Probe Prodesse, Inc. Prodesse develops molecular diagnostic products for a variety of infectious disease applications. Prodesse s results of operations have been included in the Company s consolidated financial statements beginning in October 2009.

In April 2009, the Company acquired Tepnel Life Sciences plc (Tepnel), a United Kingdom (UK) based international life sciences products and services company, now known as Gen-Probe Life Sciences Ltd. Tepnel s results of operations have been included in the Company s consolidated financial statements beginning in April 2009.

The Company translates the financial statements of its non-U.S. operations using the end-of-period exchange rates for assets and liabilities and the average exchange rates for each reporting period for results of operations. Net gains and losses resulting from the translation of foreign financial statements and the effect of exchange rates on intercompany receivables and payables of a long-term investment nature are recorded as a separate component of stockholders equity under the caption Accumulated other comprehensive income. These adjustments will affect net income (loss) upon the sale or liquidation of the underlying investment.

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Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make certain estimates and assumptions that affect the amounts reported in the consolidated financial statements. These estimates include assessing the collectability of accounts receivable, recognition of revenues, and the valuation of the following: stock-based compensation; marketable securities; equity investments in publicly and privately held companies; income tax; accrued liabilities; inventories; and goodwill and long-lived assets, including patent costs, capitalized software, purchased intangibles and licenses and manufacturing access fees. Actual results could differ from those estimates.

Segment Information

The Company currently operates in one business segment: the development, manufacturing, marketing, sales and support of molecular diagnostic products primarily to diagnose human diseases, screen donated human blood and ensure transplant compatibility. Although the Company's products comprise distinct product lines to serve different end markets within molecular diagnostics, the Company does not operate its business in operating segments. The Company is managed by a single functionally-based management team that manages all aspects of the Company's business and reports directly to the Chief Executive Officer. For all periods presented, the Company operated in a single business segment. Product sales by product line are presented in Note 11.

Revenue Recognition

The Company records shipments of its clinical diagnostic products as product sales when the product is shipped, title and risk of loss have passed to the customer, the consideration is fixed and determinable, and collection of the resulting receivable is reasonably assured.

The Company manufactures blood screening products according to demand schedules provided by its collaboration partner, Novartis Vaccines and Diagnostics, Inc. (Novartis). Upon shipment to Novartis, the Company recognizes blood screening product sales at an agreed upon transfer price and records the related cost of products sold. Based on the terms of the Company's collaboration agreement with Novartis, the Company's ultimate share of the net revenue from sales to the end user is not known until reported to the Company by Novartis. The Company then adjusts blood screening product sales upon receipt of customer revenue reports and a net payment from Novartis of amounts reflecting the Company's ultimate share of net sales by Novartis for these products, less the transfer price revenues previously recognized.

In most cases, the Company provides its instrumentation to its clinical diagnostics customers without requiring them to purchase the equipment or enter into an equipment lease. Instead, the Company recovers the cost of providing the instrumentation in the amount it charges for its diagnostic assays. The depreciation costs associated with an instrument are charged to cost of product sales on a straight-line basis over the estimated life of the instrument. The costs to maintain these instruments in the field are charged to cost of product sales as incurred.

The Company sells its instruments to Novartis for use in blood screening and records these instrument sales upon delivery since Novartis is responsible for the placement, maintenance and repair of the units with its customers. The Company also sells instruments to its clinical diagnostics customers and generally records sales of these instruments upon delivery and customer acceptance. For certain customers with non-standard payment terms, instrument sales are recorded based upon expected cash collection. Prior to delivery, each instrument is tested to meet Gen-Probe's specifications and the specifications of the United States Food and Drug Administration (FDA), and is shipped fully assembled. Customer acceptance of the Company's clinical diagnostic instrument systems requires installation and training by the Company's technical service personnel. Installation is a standard process consisting principally of uncrating, calibrating and testing the instrumentation.

The Company records revenue on its research products and services in the period during which the related costs are incurred or the services are provided. This revenue consists of outsourcing services for the pharmaceutical, biotechnology and healthcare industries, including nucleic acid purification and analysis services, as well as the sale of monoclonal antibodies.

Revenue arrangements with multiple deliverables are evaluated for proper accounting treatment. In these arrangements, the Company records revenue as separate units of accounting if the delivered items have value to the customer on a stand-alone basis, if the arrangement includes a general right of return relative to the delivered items,

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and if delivery or performance of the undelivered items is considered probable and substantially within the Company's control. For transactions entered into prior to 2011, consideration was generally allocated to each unit of accounting based on its relative fair value when objective and reliable evidence of fair value existed for all units of accounting in an arrangement. The fair value of an item was generally the price charged for the product, if the item was sold on a stand-alone basis. When the Company was unable to establish fair 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 be objectively determined for any undelivered elements. Beginning in 2011, arrangement consideration is allocated at the inception of the arrangement to all deliverables using the relative selling price method that is based on a three-tier hierarchy. The relative selling price method requires that the estimated selling price for each deliverable be based on vendor-specific objective evidence (VSOE) of fair value, which represents the price charged for each deliverable when it is sold separately or, for a deliverable not yet being sold separately, the price established by management. When VSOE of fair value is not available, third-party evidence (TPE) of fair value is acceptable, or a best estimate of selling price if neither VSOE nor TPE are available. A best estimate of selling price should be consistent with the objective of determining the price at which the Company would transact if the deliverable were sold regularly on a stand-alone basis and should also take into account market conditions and company-specific factors.

The Company recognizes collaborative research revenue over the term of various collaboration agreements, as negotiated monthly contracted amounts are earned or reimbursable costs are incurred related to those agreements. Negotiated monthly contracted amounts are earned in relative proportion to the performance required under the applicable contracts. Non-refundable license fees with stand-alone value are recognized at the time that the Company has satisfied all performance obligations. License fees without stand-alone value are recognized in combination with any undelivered performance obligations. Milestone consideration that is contingent upon achievement of a milestone in its entirety is recorded as revenue in the period in which the milestone is achieved only if the milestone meets all criteria to be considered substantive. These criteria include: (i) the consideration being earned should be commensurate with either the Company's performance to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from the Company's performance to achieve the milestone; (ii) the consideration being earned should relate solely to past performance; (iii) the consideration being earned should be reasonable relative to all deliverables and payment terms in the arrangement; and (iv) the milestone should be considered in its entirety and cannot be bifurcated into substantive and non-substantive components. Any amounts received prior to satisfying the Company's revenue recognition criteria are recorded as deferred revenue on the Company's consolidated balance sheets.

Royalty and license revenue is recognized related to the sale or use of the Company's products or technologies under license agreements with third parties. For those arrangements where royalties are reasonably estimable, the Company recognizes revenue based on estimates of royalties earned during the applicable period and adjusts for differences between the estimated and actual royalties in the following period. Historically, these adjustments have not been material. For those arrangements where royalties are not reasonably estimable, the Company recognizes revenue upon receipt of royalty statements from the applicable licensee.

Stock-based Compensation

Stock-based compensation expense is recognized for restricted stock, deferred issuance restricted stock, performance stock awards, which include awards subject to performance conditions and/or market conditions, stock options, and shares purchasable under the Company's Employee Stock Purchase Plan (ESPP). Stock-based compensation expense for restricted stock, deferred issuance restricted stock, and performance condition stock awards is measured based on the closing fair market value of the Company's common stock on the date of grant. Stock-based compensation expense for market condition stock awards is measured based on the fair value of the award on the date of grant using a Monte Carlo simulation model. The Monte Carlo simulation model utilizes multiple point variables that determine the probability of satisfying the market condition stipulated in the grant and calculates the fair value of the award.

The Company uses the Black-Scholes-Merton option pricing model to value stock options granted. The determination of the fair value of stock option awards on the date of grant using the Black-Scholes-Merton model is affected by the Company's stock price and the implied volatility on its traded options, as well as the input of other subjective assumptions. These assumptions include, but are not limited to, the expected term of stock options and the Company's expected stock price volatility over the term of the awards.

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The following table presents the weighted average assumptions used by the Company to estimate the fair value of stock options and performance stock awards granted under the Company's equity incentive plans and the shares purchasable under the Company's ESPP, as well as the resulting average fair values for the three and nine month periods ended September 30, 2011 and 2010:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Stock option plans				
Risk-free interest rate	1.5%	1.5%	1.7%	2.1%
Volatility	32.4%	31.7%	30.9%	32.0%
Dividend yield				
Expected term (years)	4.3	4.4	4.3	4.4
Resulting average fair value	\$ 17.69	\$ 12.97	\$ 18.05	\$ 12.79
Performance stock awards ⁽¹⁾				
Risk-free interest rate			1.3%	
Volatility			33.4%	
Dividend yield				
Expected term (years)			2.9	
Resulting average fair value	\$	\$	\$ 82.58	\$
Employee stock purchase plan				
Risk-free interest rate	0.1%	0.2%	0.1%	0.2%
Volatility	34.6%	21.5%	27.9%	24.0%
Dividend yield				
Expected term (years)	0.5	0.5	0.5	0.5
Resulting average fair value	\$ 17.26	\$ 9.62	\$ 14.72	\$ 9.63

⁽¹⁾ These assumptions apply to the Company's market condition stock awards granted in February 2011. Performance condition stock awards granted in February 2010 were valued at \$42.66 per share based on the closing fair market value of the Company's common stock on the date of grant.

The Company's unrecognized stock-based compensation expense as of September 30, 2011, before income taxes and adjusted for estimated forfeitures, related to outstanding unvested share-based payment awards was as follows (in thousands, except number of years):

Awards	Weighted Average Remaining Expense Life (Years)	Unrecognized Expense as of September 30, 2011
Stock options	2.6	\$ 29,472
Performance stock awards	2.3	5,321
Restricted stock	1.4	2,144
Deferred issuance restricted stock	1.4	620
Employee stock purchase plan	0.2	102
Total		\$ 37,659

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The following table summarizes the stock-based compensation expense that the Company recorded in its consolidated statements of income for the three and nine month periods ended September 30, 2011 and 2010 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Cost of product sales	\$ 773	\$ 946	\$ 2,355	\$ 2,817
Research and development	1,952	1,783	5,805	5,313
Marketing and sales	535	682	1,881	2,319
General and administrative	3,107	2,788	9,185	8,089
Total	\$ 6,367	\$ 6,199	\$ 19,226	\$ 18,538

Net Income (Loss) Per Share

Diluted net income (loss) per share is reported based on the more dilutive of the treasury stock or the two-class method. Under the two-class method, net income (loss) is allocated to common stock and participating securities. The Company's restricted stock, deferred issuance restricted stock and performance stock awards meet the definition of participating securities. Basic net income (loss) per share under the two-class method is computed by dividing net income (loss) adjusted for earnings allocated to unvested stockholders for the period by the weighted average number of common shares outstanding during the period. Diluted net income (loss) per share under the two-class method is computed by dividing net income (loss) adjusted for earnings allocated to unvested stockholders for the period by the weighted average number of common and common equivalent shares outstanding during the period. The Company excludes stock options from the calculation of diluted net income per share when the combined exercise price, unrecognized stock-based compensation and assumed tax benefits upon exercise are greater than the average market price for the Company's common stock because their effect is anti-dilutive. Potentially dilutive securities totaling approximately 5,979,000 and 4,065,000 shares for the three month periods ended September 30, 2011 and 2010, respectively, and 906,000 and 4,390,000 shares for the nine month periods ended September 30, 2011 and 2010, respectively, were excluded from the calculations of diluted earnings per share (EPS) below because of their anti-dilutive effect.

The following table sets forth the computation of basic and diluted EPS for the three and nine month periods ended September 30, 2011 and 2010 (in thousands, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Basic Net Income (Loss) per Share				
Net income (loss)	\$ (15,356)	\$ 27,396	\$ 30,265	\$ 79,699
Less: income allocated to participating securities		(99)	(43)	(327)
Net income (loss) allocated to common stockholders	\$ (15,356)	\$ 27,297	\$ 30,222	\$ 79,372
Weighted average common shares outstanding - basic	47,092	48,254	47,613	48,796
Net income (loss) per share - basic	\$ (0.33)	\$ 0.57	\$ 0.63	\$ 1.63
Diluted Net Income (Loss) per Share				
Net income (loss)	\$ (15,356)	\$ 27,396	\$ 30,265	\$ 79,699
Less: income allocated to participating securities		(99)	(42)	(324)
Net income (loss) allocated to common stockholders	\$ (15,356)	\$ 27,297	\$ 30,223	\$ 79,375
Weighted average common shares outstanding - basic	47,092	48,254	47,613	48,796
Dilutive securities		425	1,200	461