GENOMIC HEALTH INC
Form 10-Q
August 09, 2012
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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 June 30, 2012

Or

o 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: 000-51541

GENOMIC HEALTH, INC.

(Exact name of registrant as specified in its charter)

Delaware	**77-0552594**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

301 Penobscot Drive

Redwood City, California 94063

(Address of principal executive offices) (Zip Code)

(650) 556-9300

(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 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 o

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 o

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 o	Accelerated filer x
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES o NO x

The number of outstanding shares of the registrant s Common Stock, $0.0001 par value, was 30,436,528 as of July 31, 2012.

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PART 1: FINANCIAL INFORMATION

Item 1. Financial Statements

GENOMIC HEALTH, INC.

Condensed Consolidated Balance Sheets

(In thousands)

(Unaudited)

	June 30, 2012	December 31, 2011
ASSETS		
Current assets:		
Cash and cash equivalents	$ 57,014	$ 32,869
Short-term marketable securities	55,570	67,605
Accounts receivable (net of allowance for doubtful accounts; 2012 - $1,145, 2011 - $1,206)	21,699	21,077
Prepaid expenses and other current assets	8,206	7,444
Total current assets	142,489	128,995
Long-term marketable securities	1,291	
Property and equipment, net	10,276	9,443
Other assets	4,923	4,560
Total assets	$ 158,979	$ 142,998
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 3,489	$ 7,025
Accrued compensation	9,881	9,574
Accrued license fees	1,889	1,947
Accrued expenses and other current liabilities	5,765	5,501
Deferred revenues current portion	1,403	1,407
Other current liabilities	93	685
Total current liabilities	22,520	26,139
Deferred revenues long-term portion		211
Other liabilities	2,205	1,289
Commitments (Note 5)		
Stockholders equity:		
Common stock	3	3
Additional paid-in capital	297,437	281,147
Accumulated other comprehensive income loss	(2)	(30)
Accumulated deficit	(163,184)	(165,761)
Total stockholders equity	134,254	115,359
Total liabilities and stockholders equity	$ 158,979	$ 142,998

See accompanying notes.

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GENOMIC HEALTH, INC.

Condensed Consolidated Statements of Income

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Revenues:				
Product revenues	$ 57,185	$ 50,493	$ 115,088	$ 99,951
Contract revenues	446	353	1,010	705
Total revenues	57,631	50,846	116,098	100,656
Operating expenses:				
Cost of product revenues	9,013	8,226	18,340	17,285
Research and development	11,579	9,879	23,508	19,971
Selling and marketing	23,765	20,529	48,131	41,064
General and administrative	11,436	9,852	23,411	20,208
Total operating expenses	55,793	48,486	113,390	98,528
Income from operations	1,838	2,360	2,708	2,128
Interest income	74	75	149	140
Other income (expense), net	(73)	(28)	(145)	(78)
Income before income taxes	1,839	2,407	2,712	2,190
Income tax expense	38	59	135	128
Net income	$ 1,801	$ 2,348	$ 2,577	$ 2,062
Basic net income per share	$ 0.06	$ 0.08	$ 0.09	$ 0.07
Diluted net income per share	$ 0.06	$ 0.08	$ 0.08	$ 0.07
Shares used in computing basic net income per share	30,204	29,332	30,057	29,219
Shares used in computing diluted net income per share	32,064	30,870	31,835	30,591

See accompanying notes.

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GENOMIC HEALTH, INC.

Condensed Consolidated Statements of Comprehensive Income

(In thousands)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	**2011**	**2012**	**2011**
Net income	$ 1,801	$ 2,348	$ 2,577	$ 2,062
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale marketable securities	(49)	39	28	38
Comprehensive income	$ 1,752	$ 2,387	$ 2,605	$ 2,100

See accompanying notes.

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GENOMIC HEALTH, INC.

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Six Months Ended June 30,	
	2012	**2011**
Operating activities		
Net income	$ 2,577	$ 2,062
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	2,765	3,707
Stock-based compensation	7,405	5,898
Share of loss of equity method investee	98	72
Changes in assets and liabilities:		
Accounts receivable	(622)	(5,063)
Prepaid expenses and other assets	(901)	46
Accounts payable	(3,536)	(2,073)
Accrued compensation	307	892
Accrued expenses and other liabilities	958	(1,254)
Deferred revenues	(670)	(643)
Net cash provided by operating activities	8,381	3,644
Investing activities		
Purchases of property and equipment	(3,493)	(2,841)
Purchases of marketable securities	(38,388)	(67,565)
Maturities of marketable securities	49,160	56,072
Purchase of other investments	(400)	(2,300)
Net cash provided by (used in) investing activities	6,879	(16,634)
Financing activities		
Net proceeds from issuance of common stock under stock plans	8,885	5,557
Net cash provided by financing activities	8,885	5,557
Net increase (decrease) in cash and cash equivalents	24,145	(7,433)
Cash and cash equivalents at the beginning of the period	32,869	31,183
Cash and cash equivalents at the end of the period	$ 57,014	$ 23,750
Supplemental disclosure of cash flow information		
Cash paid for income taxes	$ 56	$ 73

See accompanying notes.

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GENOMIC HEALTH, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2012

(Unaudited)

Note 1. Organization and Summary of Significant Accounting Policies

The Company

Genomic Health, Inc. (the Company) is a global health company that provides actionable genomic information to personalize genomic health decisions. The Company develops and globally commercializes genomic-based clinical laboratory services that analyze the underlying biology of cancer, allowing physicians and patients to make individualized treatment decisions. The Company was incorporated in Delaware in August 2000. The Company s first product, the Onco*type* DX invasive breast cancer test, was launched in 2004 and is used for early stage invasive breast cancer patients to predict the likelihood of breast cancer recurrence and the likelihood of chemotherapy benefit. In January 2010, the Company launched its second product, the Onco*type* DX colon cancer test, which is used to predict the likelihood of colon cancer recurrence in patients with stage II disease. In late December 2011, the Company made Onco*type* DX available for patients with ductal carcinoma in situ (DCIS), a pre-invasive form of breast cancer. This test provides a DCIS score that is used to predict the likelihood of local recurrence. In June 2012, the Company extended its offering of the Onco*type* DX colon cancer test to certain patients with stage III disease.

Principles of Consolidation

The condensed consolidated financial statements include all the accounts of the Company and its wholly-owned subsidiaries. As of June 30, 2012, the Company had four wholly-owned subsidiaries. Genomic Health International Sarl, which was established in Switzerland in 2009, and Genomic Health International Holdings, LLC, which was established in Delaware in 2010, support the Company s international sales and marketing efforts, InVitae Corporation, which was established in March 2012 and Oncotype Laboratories, Inc., which was established in Delaware in 2003, and is inactive. Genomic Health International Holdings, LLC has three wholly-owned subsidiaries: Genomic Health U.K., Ltd. and Genomic Health Germany GmbH, which were established in 2011 and Genomic Health Canada, which was established in 2012. The functional currency for the Company s wholly-owned subsidiaries incorporated outside of the United States is the U.S. dollar. All significant intercompany balances and transactions have been eliminated.

Basis of Presentation and Use of Estimates

The accompanying interim period condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP). The condensed consolidated balance sheet as of June 30, 2012, the condensed consolidated statements of income for the three and six months ended June 30, 2012 and 2011, the condensed consolidated statements of comprehensive income for the three and six months ended June 30, 2012 and 2011, and the condensed consolidated statements of cash flows for

the six months ended June 30, 2012 and 2011 are unaudited, but include all adjustments, consisting only of normal recurring adjustments, which the Company considers necessary for a fair presentation of its financial position, operating results and cash flows for the periods presented. The condensed consolidated balance sheet at December 31, 2011 has been derived from audited financial statements, but it does not include certain information and notes required by GAAP for complete consolidated financial statements.

The preparation of financial statements in conformity with GAAP requires management to make judgments, assumptions and estimates that affect the amounts reported in the Company s condensed consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates.

The accompanying interim period condensed consolidated financial statements and related financial information should be read in conjunction with the audited consolidated financial statements and the related notes thereto included in the Company s Annual Report on Form 10-K for the year ended December 31, 2011.

Revenue Recognition

The Company derives its revenues from product sales and contract research arrangements. The majority of the Company s historical product revenues have been derived from the sale of the Onco*type* DX breast cancer test. The Company generally bills third-party payors upon generation and delivery of a patient report to the physician. As such, the Company takes assignment of benefits and the risk of collection with the third-party payor. The Company usually bills the patient directly for amounts owed after multiple requests for payment have been denied or only partially paid by the insurance carrier. The Company pursues case-by-case reimbursement where policies are not in place or payment history has not been established.

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The Company s product revenues for tests performed are recognized when the following revenue recognition criteria are met: (1) persuasive evidence an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectibility is reasonably assured. Criterion (1) is satisfied when the Company has an arrangement to pay or a contract with the payor in place addressing reimbursement for the Onco*type* DX test. In the absence of such arrangements, the Company considers that criterion (1) is satisfied when a third-party payor pays the Company for the test performed. Criterion (2) is satisfied when the Company performs the test and generates and delivers to the physician, or makes available on its web portal, a patient report. Determinations of criteria (3) and (4) are based on management s judgments regarding whether the fee charged for products or services delivered is fixed or determinable, and the collectibility of those fees under any contract or arrangement. When evaluating collectibility, the Company considers whether it has sufficient history to reliably estimate a payor s individual payment patterns. Based upon at least several months of payment history, the Company reviews the number of tests paid against the number of tests billed and the payor s outstanding balance for unpaid tests to determine whether payments are being made at a consistently high percentage of tests billed and at appropriate amounts given the contracted payment amount. To the extent all criteria set forth above are not met when test results are delivered, product revenues are recognized when cash is received from the payor.

The Company has established exclusive distribution agreements for one or more of its Onco*type* DX tests with 20 distributors covering more than 80 countries. The distributor generally provides certain marketing and administrative services to the Company within its territory. As a condition of these agreements, the distributor generally pays the Company an agreed upon fee per test and the Company processes the tests. The same revenue recognition criteria described above generally apply to tests received through distributors. To the extent all criteria set forth above are not met when test results are delivered, product revenues are generally recognized when cash is received from the distributor.

From time to time, the Company receives requests for refunds of payments, generally due to overpayments made by third-party payors. Upon becoming aware of a refund request, the Company establishes an accrued liability for tests covered by the refund request until such time as the Company determines whether or not a refund is due. Accrued refunds were $564,000 and $562,000 at June 30, 2012 and December 31, 2011, respectively.

Contract revenues are generally derived from studies conducted with biopharmaceutical and pharmaceutical companies. The specific methodology for revenue recognition is determined on a case-by-case basis according to the facts and circumstances applicable to a given contract. Under certain contracts, the Company s input, measured in terms of full-time equivalent level of effort or running a set of assays through its clinical reference laboratory under a contractual protocol, triggers payment obligations, and revenues are recognized as costs are incurred or assays are processed. Certain contracts have payments that are triggered as milestones are completed, such as completion of a successful set of experiments. Milestones are assessed on an individual basis and revenue is recognized when these milestones are achieved, as evidenced by acknowledgment from collaborators, provided that (1) the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement and (2) the milestone payment is non-refundable. Where separate milestones do not meet these criteria, the Company typically defaults to a performance-based model, such as revenue recognition following delivery of effort as compared to an estimate of total expected effort.

Advance payments received in excess of revenues recognized are classified as deferred revenue until such time as the revenue recognition criteria have been met.

Allowance for Doubtful Accounts

The Company accrues an allowance for doubtful accounts against its accounts receivable based on estimates consistent with historical payment experience. Bad debt expense is included in general and administrative expense on the Company s condensed consolidated statements of income.

Accounts receivable are written off against the allowance when the appeals process is exhausted, when an unfavorable coverage decision is received or when there is other substantive evidence that the account will not be paid. The Company s allowance for doubtful accounts as of June 30, 2012 and December 31, 2011 was $1.1 million and $1.2 million, respectively. Write-offs for doubtful accounts of $706,000 and $1.6 million were recorded against the allowance during the three and six months ended June 30, 2012, respectively, and write-offs of $714,000 and $1.5 million were recorded during the three and six months ended June 30, 2011, respectively. Bad debt expense was $884,000 and $1.6 million for the three and six months ended June 30, 2012, respectively, and $736,000 and $1.6 million for the three and six months ended June 30, 2011, respectively.

Research and Development Expenses

Research and development expenses consist of costs incurred to develop technology and carry out clinical studies and include salaries and benefits, reagents and supplies used in research and development laboratory work, infrastructure expenses, including allocated facility occupancy and information technology costs, contract services, and other outside costs. Research and development

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expenses also include costs related to activities performed under contracts with biopharmaceutical and pharmaceutical companies. Research and development costs are expensed as incurred.

The Company enters into collaboration and clinical trial agreements with clinical collaborators and records the costs associated with these arrangements as research and development expenses. The Company records accruals for estimated study costs consisting of work performed by its collaborators under contract terms. Advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized and recognized as expense as the goods are delivered or the related services are performed.

Income Taxes

The Company uses the liability method for income taxes, whereby deferred income taxes are provided on items recognized for financial reporting purposes over different periods than for income tax purposes. Valuation allowances are provided when the expected realization of tax assets does not meet a more-likely-than-not criterion.

The Company accounts for uncertain income tax positions using a benefit recognition model with a two-step approach, a more-likely-than-not recognition criterion and a measurement attribute that measures the position as the largest amount of tax benefit that is greater than 50% likely of being realized upon ultimate settlement, in accordance with the accounting guidance for uncertain tax positions. If it is not more likely than not that the benefit will be sustained on its technical merits, no benefit is recorded. Uncertain tax positions that relate only to timing of when an item is included on a tax return are considered to have met the recognition threshold. The Company recognizes accrued interest and penalties related to unrecognized tax benefits in income tax expense when and if incurred. See Note 8, Income Taxes, for additional information regarding unrecognized tax benefits.

Investments in Privately Held Companies

The Company determines whether its investments in privately held companies are debt or equity based on their characteristics, in accordance with accounting guidance for investments. The Company also evaluates the investee to determine if the entity is a variable interest entity (VIE) and, if so, whether the Company is the primary beneficiary of the VIE, in order to determine whether consolidation of the VIE is required in accordance with accounting guidance for consolidations. If consolidation is not required and the Company owns less than 50.1% of the voting interest of the entity, the investment is evaluated to determine if the equity method of accounting should be applied. The equity method applies to investments in common stock or in-substance common stock representing 20% or more of the voting interests of an entity. If the equity method does not apply, investments in privately held companies determined to be equity securities are accounted for using the cost method. Investments in privately held companies determined to be debt securities are accounted for as available-for-sale or held-to-maturity securities, in accordance with accounting guidance for investments.

In December 2010, the Company invested $500,000 in the preferred stock of a private company representing 21% of the entity s outstanding voting shares. The Company determined that is was not the primary beneficiary of this VIE and, accordingly, applied the equity method of accounting. During the quarter ended June 30, 2012, the Company invested an additional $400,000 in the preferred stock of this company as part of a new equity financing, reducing the Company s holdings to approximately 16%. As of June 30, 2012, as a result of the Company s ownership falling below 20% and not having the ability to exercise influence over the investee entity, the Company changed its method of accounting for

this investment to the cost method. Therefore, the net carrying value of this investment of $637,000 is reflected at cost at June 30, 2012 and is subject to impairment evaluation on a quarterly basis.

In March 2011, the Company invested $2.3 million in the redeemable preferred stock of a private company representing 21% of the entity s outstanding voting shares. The Company determined that the investment was a held-to-maturity debt security and that the investee was not subject to consolidation. The investment was recorded at cost and is subject to impairment evaluation on a quarterly basis. The fair value of a cost method investment is not estimated if there are no identified events or changes in circumstances that may have a significant adverse effect on the fair value of the investment. The carrying value of this investment was $2.3 million at June 30, 2012 and December 31, 2011, respectively, and no impairment was recognized through June 30, 2012.

The Company s investments in privately held companies were $2.9 million and $2.6 million at June 30, 2012 and December 31, 2011, respectively, and were included in other assets on the Company s condensed consolidated balance sheets.

Recently Issued Accounting Pronouncements

In June 2011, the Financial Accounting Standards Board (FASB) issued authoritative guidance requiring companies to present items of net income, items of other comprehensive income and total comprehensive income in one continuous statement or two consecutive statements. This guidance eliminates the option for companies to present other comprehensive income in the statement of

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stockholders equity. This guidance is effective for the Company for interim and annual periods beginning January 1, 2012. In December 2011, FASB released an update that deferred a portion of the new accounting requirements for comprehensive income. As this guidance provides only presentation requirements, the adoption of this guidance does not impact the Company s financial condition or results of operations. The Company adopted this standard in January 2012, as reflected by the inclusion of the Condensed Consolidated Statements of Comprehensive Income as part of its Condensed Consolidated Financial Statements.

In June 2011, the FASB issued amendments to authoritative guidance for measuring fair value when required or permitted by other accounting standards. The amendments are intended to result in common fair value measurement and disclosure requirements under GAAP and International Financial Reporting Standards. Some of the amendments clarify the FASB s intent about the application of existing fair value measurement requirements. Other amendments change a particular principle or requirement for measuring fair value or for disclosing information about fair value measurements. This amended guidance, which the Company does not expect to have a material impact on its financial condition and results of operations, is effective for the Company for interim and annual periods beginning January 1, 2012. The Company adopted this standard in January 2012, as reflected in Note 3, Fair Value Measurements, of its Condensed Consolidated Financial Statements.

Note 2. Net Income Per Share

Basic net income per share is calculated by dividing net income for the period by the weighted-average number of common shares outstanding for the period without consideration of potential common shares. Diluted net income per share is calculated by dividing net income by the weighted-average number of common shares outstanding for the period and dilutive potential common shares for the period determined using the treasury-stock method. For purposes of this calculation, options to purchase common stock and restricted stock unit awards which are considered to be potential common shares and are anti-dilutive are not included in the calculation of diluted net income per share because their effect is anti-dilutive.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
	(In thousands)			
Numerator:				
Net income	$ 1,801	$ 2,348	$ 2,577	$