Hologic Announces First Quarter Fiscal 2013 Operating Results

The Associated Press

Hologic, Inc. (Hologic or the Company) (NASDAQ: HOLX), a leading developer, manufacturer and supplier of premium diagnostics products, medical imaging systems and surgical products dedicated to serving the healthcare needs of women, today announced its results for the first fiscal quarter ended December 29, 2012.

Highlights of the Quarter Include: -- Revenues of $631.4 million, net of a $(13.3) million adjustment primarily related to contingent revenue earned and received under Gen-Probe Incorporated's (Gen-Probe) collaboration agreement with Novartis.

-- Non-GAAP adjusted revenues of $644.6 million, increased to include the aforementioned $13.3 million net adjustment.

-- Year-over-year revenue growth in the Company's three primary business segments, Breast Health, Diagnostics and GYN Surgical, which represented over 96% of revenues.

-- Net income of $3.1 million, or $0.01 per diluted share, calculated in accordance with U.S. generally accepted accounting principles (GAAP).

-- Non-GAAP adjusted net income of $101.8 million, or $0.38 per diluted share, and adjusted EBITDA (non-GAAP adjusted earnings before interest, taxes, depreciation and amortization) of $227.5 million.

-- U.S. Food and Drug Administration (FDA) Approval of the APTIMA 16 18/45 Genotype Assay for use on the TIGRIS System announced on October 16, 2012.

-- $60 million cash settlement received on December 28, 2012 from K-V Pharmaceutical Company (KV) in full satisfaction and discharge of all Hologic claims against KV.

Highlights Subsequent to the Quarter Include: -- Oslo study published on January 7, 2013, in Radiology, reporting the addition of the Company's 3D mammography screening technology to a 2D breast screening exam significantly increased cancer detection while reducing the number of false positives.

-- FDA clearance of the Company's APTIMA Trichomonas vaginalis Assay for use on its fully-automated PANTHER System announced on January 14, 2013.

-- FDA clearance of the Company's contrast-enhanced digital mammography for improved visualization of breast tissue announced today.

-- Definitive agreement announced on January 3, 2013, to sell the Company's LIFECODES business to Immucor, Inc. for $85 million in cash, subject to adjustment, and $10 million in a potential contingent payment.

A reconciliation of historical GAAP to non-GAAP results is included as an attachment to this press release.

"We began fiscal 2013 with great promise and we are confident our combination with Gen-Probe positions us to continue creating significant value for all of our stakeholders," said Rob Cascella, President and Chief Executive Officer. "During the quarter, we leveraged our expanded product portfolio to drive year-over-year growth in our Diagnostics, Breast Health and GYN Surgical segments. We are executing the strategy we outlined at the beginning of the year and we believe we are well positioned to build on our momentum for the remainder of fiscal 2013 and beyond." First Quarter Fiscal 2013 Operating Results Overview: First quarter fiscal 2013 revenues totaled $631.4 million. Excluding the effect of a net adjustment of $(13.3), primarily related to purchase accounting, non-GAAP adjusted revenues were $644.6 million, an increase of 36.4% compared to revenues of $472.7 million in the first quarter of fiscal 2012. This adjustment primarily related to contingent revenue earned and received under Gen-Probe's collaboration agreement with Novartis, for which the cash was collected by the Company following the acquisition. If not for this purchase accounting adjustment, the Company would have recognized revenues on these receipts in the first quarter of fiscal 2013.

The increase in revenues was driven by: -- Growth in Diagnostics non-GAAP adjusted revenues of $165.1 million, or 107.2%, primarily from the inclusion of Gen-Probe revenues for a full quarter and an increase in Hologic's legacy Diagnostics revenues.

Legacy Diagnostics revenue growth occurred primarily in the molecular diagnostics product lines and international ThinPrep sales; -- Growth in Breast Health revenues of $5.5 million, or 2.5%, primarily from an increase in service revenue from the Company's increased installed base of digital mammography systems, partially offset by a reduction in product revenues; and -- Growth in GYN Surgical revenues of $2.4 million, or 3.0%, primarily from an increase in MyoSure hysteroscopic tissue removal (MyoSure) system sales, partially offset by the Company's decision in the second quarter of fiscal 2012 to discontinue sales of its Adiana permanent contraception (Adiana) system.

The impact on revenues from changes in foreign currencies compared with the first quarter of fiscal 2012 was a reduction of approximately $0.3 million.

First quarter fiscal 2013 net income was $3.1 million, or $0.01 per diluted share, compared with net income of $20.8 million, or $0.08 per diluted share, in the first quarter of fiscal 2012. The Company's non-GAAP adjusted net income increased 13.0% to $101.8 million, or $0.38 per diluted share, in the first quarter of fiscal 2013 compared to $90.0 million, or $0.34 per diluted share, for the same period in the prior year. Included in the Company's non-GAAP adjusted net income for the first quarter of fiscal 2013 was a benefit of $0.01 from the recently-reinstated

federal research tax credit. For GAAP purposes, this benefit will be reflected in results beginning in the second fiscal quarter.

Non-GAAP adjusted revenues, non-GAAP adjusted net income, non-GAAP adjusted earnings per diluted share (EPS), and adjusted EBITDA are non-GAAP financial measures. The Company's definitions of these non-GAAP financial measures, and the reconciliations of these historical measures to the Company's comparable GAAP financial measures for the periods presented, are set forth in the supplemental information attached to this press release. When analyzing the Company's operating performance, investors should not consider these non-GAAP measures as a substitute for the comparable financial measures prepared in accordance with GAAP.

"Looking ahead, we believe Hologic's diverse, innovative products will continue to gain traction in the marketplace by exceeding the expectations of our customers and addressing the needs of our patients," said Rob Cascella. "We have leadership across our business segments and the resources and capabilities to support our long-term growth strategy." First Quarter Fiscal 2013 Revenue Overview by Segment (As Compared to the First Quarter Fiscal 2012): -- Diagnostics revenues totaled $305.9 million in the current quarter, net of the $13.3 million reduction primarily for the effect of purchase accounting related to Gen-Probe's collaboration agreement with Novartis that was eliminated under GAAP, compared to $154.1 million in the prior year. Including the $13.3 million, non-GAAP adjusted revenues totaled $319.2 million, an increase of 107.2%. Sales growth was driven primarily by the inclusion of Gen-Probe revenues for a full quarter and, to a lesser extent, strong growth in Hologic's legacy molecular diagnostics revenues as well as an increase in international ThinPrep sales.

-- Breast Health revenues totaled $220.8 million in the current quarter compared to $215.4 million in the prior year, an increase of 2.5%. Revenue growth was driven by an $8.6 million, or 12.2%, increase in service revenues from the Company's growing installed base of digital mammography systems, partially offset by a reduction in product revenues of $3.2 million, or 2.2%.

-- GYN Surgical revenues totaled $80.9 million in the current quarter compared to $78.5 million in the prior year, an increase of 3.0%. The increase was driven primarily by an increase in MyoSure system sales, partially offset by a $5.1 million reduction in Adiana system revenues due to the Company's decision in the second quarter of fiscal 2012 to discontinue sales of that product line and, to a lesser extent, a slight decrease in NovaSure system sales. Excluding Adiana revenues in both periods, the increase in GYN Surgical revenues was approximately 10.1%.

-- Skeletal Health revenues totaled $23.7 million in the current quarter compared to $24.7 million in the prior year, a decrease of 4.1%. This decrease was primarily the result of a slight reduction in product and service revenues.

Publication of the Oslo Tomosynthesis Screening Trial Results: On January 7, 2013, results from the first large-scale, peer-reviewed prospective clinical study of its kind were published online, in advance of print, by Radiology, the Radiological Society of

North America scientific journal. The researchers reported that the addition of Hologic's 3D mammography (breast tomosynthesis) screening technology to a 2D breast screening exam significantly increased cancer detection, particularly for invasive cancers, and simultaneously decreased the false-positive rates. Some of the significant findings reported include: -- A 40% increase in the detection of invasive breast cancers -- A 27% increase in the detection of all cancers (invasive and in situ cancers combined) -- A 15% decrease in false-positive rates -- An increase in cancer detection across all breast tissue densities, from dense to fatty -- All of the above achieved with no increase in the detection of ductal carcinoma in situ, which is non-invasive and cited as potentially being over-diagnosed.

New Products: APTIMA HPV 16 18/45 Genotype Assay for use on TIGRIS: On October 16, 2012, the Company announced FDA approval of its APTIMA HPV 16 18/45 Genotype Assay for use on its TIGRIS System. Hologic's APTIMA HPV 16 18/45 Genotype Assay is the first test FDA-approved for genotyping all three human papillomavirus (HPV) types 16, 18 and/or 45, which are associated with approximately 80% of all invasive cervical cancers worldwide. Detecting these HPV types provides health care professionals with more information regarding a patient's risk of subsequently developing cervical cancer. The APTIMA HPV Assay received FDA approval in 2011 and was CE marked in 2008.

APTIMA Trichomonas vaginalis Assay for use on PANTHER: On January 14, 2013, the Company announced FDA clearance of its APTIMA Trichomonas vaginalis Assay for use on its fully-automated PANTHER System. The APTIMA Trichomonas vaginalis Assay, first cleared for use on Hologic's TIGRIS System in April 2011, remains the only FDA-cleared amplified nucleic acid test on the market specifically cleared to detect Trichomonas vaginalis. Trichomonas is a sexually transmitted parasite estimated to cause 7.4 million infections in the U.S.

annually and has been linked to several serious health issues.

Hologic's assay may be used to test clinician-collected endocervical or vaginal swabs and specimens collected in Hologic's ThinPrep vial from symptomatic or asymptomatic women.

Contrast-Enhanced Digital Mammography System: Today the Company announced FDA clearance of its contrast-enhanced digital mammography (CEDM) system. CEDM is a procedure in which a contrast agent is injected into the patient prior to the mammography exam in order to enhance breast imaging. This imaging technique can be used as an adjunct to digital mammography to localize a known or suspected lesion. CEDM has the potential for better sensitivity versus conventional full-field digital mammography, or 2D mammography, alone.

The Company intends to launch this product later this fiscal year as an upgrade to the Company's Dimensions platform.

Definitive Agreement to Sell LIFECODES: On January 3, 2013, the Company announced it signed a definitive agreement to sell its LIFECODES business unit to Immucor, Inc. for $85 million in cash at closing, subject to certain adjustments, and

have the opportunity to earn a contingent payment of $10 million based on achievement of certain financial targets for calendar year 2013. The transaction is subject to customary closing conditions, including expiration of the applicable waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, as well as international regulatory review. The transaction is expected to close during the second fiscal quarter.

Settlement of K-V Pharmaceutical Claim: Hologic had previously submitted claims against K-V Pharmaceutical Company arising out of its Asset Purchase Agreement with KV, relating to Hologic's sale of its pharmaceutical product Makena and related assets to KV. On December 28, 2012, KV paid Hologic $60 million in full satisfaction and discharge of all Hologic claims against KV.

Hologic recognized a gain of $53.9 million, net of related costs, in the Company's first fiscal quarter. This gain has been excluded from the Company's non-GAAP net income.

Federal Research Tax Credit: On January 2, 2013, federal legislation was passed that extends the federal research tax credit for two years, starting retroactively from January 1, 2012. The Company will record this cumulative adjustment in its GAAP results in the second quarter of fiscal 2013.

Financial Guidance: The Company's guidance includes current operations, including revenues from its approved/cleared products and its recently acquired businesses.

Second Quarter Fiscal 2013 (Quarter Ending March 30, 2013): -- The Company expects second quarter fiscal 2013 non-GAAP adjusted revenues of $635 million to $640 million (excludes an expected purchase accounting reduction of $5.2 million related to the Novartis collaboration). Year-over-year, this represents an expected increase of 35% to 36% over second quarter fiscal 2012 revenues of $471.2 million. The increase is driven primarily by the inclusion of revenues related to the Gen-Probe acquisition, the continued ramp-up of new products including the Dimensions, PANTHER, and MyoSure systems and an expected overall improvement in each of the Company's operating segments, partially offset by an elimination in Adiana system revenues and revenues associated with LIFECODES which is expected to be sold during the quarter.

-- The Company expects non-GAAP adjusted EPS of $0.33 to $0.34. This reflects the expected benefit of approximately $0.01 from the recently-reinstated federal research tax credit, offset by the expected impact of the medical device excise tax which is expected to be $0.02 dilutive.

Fiscal 2013 (Year Ending September 28, 2013): -- The Company is reaffirming expected fiscal 2013 non-GAAP adjusted revenues of $2.61 billion to $2.64 billion. Year-over-year this represents an expected increase of 30% to 31% over fiscal 2012 non-GAAP revenues of $2.01 billion. This increase is driven primarily by revenues related to the Gen-Probe acquisition and, to a lesser extent, increases in the Breast Health, GYN Surgical and legacy Diagnostics segments, partially offset by a reduction in Adiana system revenues.

-- The Company expects non-GAAP adjusted EPS of $1.58 to $1.60. This is $0.02 higher than the guidance provided on November 12, 2012 due to the recently-reinstated federal research tax credit, partially offset by a slight increase in expected operating expenses.

Hologic may not generate expected revenues and may incur expenses or charges, realize income or gains, or execute acquisitions or dispositions in fiscal 2013 that could cause actual results to vary from the guidance above. In addition, the Company is continuing to monitor the effects of the U.S., European and general worldwide economic and regulatory conditions and related uncertainties, including the implementation of healthcare cost containment measures and healthcare reform legislation, as well as foreign currency fluctuations, which, along with other uncertainties facing the Company's business including those referenced elsewhere herein and its filings with the Securities and Exchange Commission, could adversely affect anticipated results.

Conference Call and Webcast: Hologic's management will host a conference call on Monday, February 4, 2013, at 5:00 p.m. (Eastern) to discuss first quarter fiscal year 2013 operating results. Interested participants may listen to the call by dialing 888-523-1227 or 719-457-2632 for international callers and referencing code 5124529 approximately 15 minutes prior to the call.

For those unable to participate in the live broadcast, a replay will be available one hour after the call ends through Friday, February 22, 2013, at 888-203-1112 or 719-457-0820 for international callers, access code 5124529. The Company will also provide a live webcast of the call. Interested participants may access the webcast on the Company's website at www.hologic.com/investors-overview [1]. A PowerPoint presentation related to the conference call has been posted to the site.

About Hologic, Inc.: Hologic, Inc. is a leading developer, manufacturer and supplier of premium diagnostic products, medical imaging systems, and surgical products. The Company operates four core business units focused on breast health, diagnostics, GYN surgical and skeletal health. With a comprehensive suite of technologies and a robust research and development program, Hologic is committed to improving lives. The Company is headquartered in Massachusetts. For more information, visit www.hologic.com [2].

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Forward-Looking Statement Disclaimer: This News Release contains forward-looking information that involves risks and uncertainties, including statements about the Company's plans, objectives, expectations and intentions. Such statements include, without limitation: financial or other information included herein based upon or otherwise incorporating judgments or estimates relating to future performance, events or expectations; the Company's positioning, resources, capabilities, and

expectations for future growth; the anticipated benefits of the Gen-Probe acquisition; and the Company's outlook and financial and other guidance. These forward-looking statements are based upon assumptions made by the Company as of the date hereof and are subject to known and unknown risks and uncertainties that could cause actual results to differ materially from those anticipated.

Risks and uncertainties that could adversely affect the Company's business and prospects, and otherwise cause actual results to differ materially from those anticipated, include without limitation: U.S., European and general worldwide economic conditions and related uncertainties; the Company's reliance on third-party reimbursement policies to support the sales and market acceptance of its products, including the possible adverse impact of government regulation and changes in the availability and amount of reimbursement and uncertainties for new products or product enhancements; uncertainties regarding the recently enacted or future healthcare reform legislation, including associated tax provisions, or budget reduction or other cost containment efforts; changes in guidelines, recommendations and studies published by various organizations that could affect the use of the Company's products; uncertainties inherent in the development of new products and the enhancement of existing products, including FDA approval and/or clearance and other regulatory risks, technical risks, cost overruns and delays; the risk that products may contain undetected errors or defects or otherwise not perform as anticipated; risks associated with acquisitions, including without limitation, the Company's ability to successfully integrate acquired businesses, the risks that the acquired businesses may not operate as effectively and efficiently as expected even if otherwise successfully integrated, the risks that acquisitions may involve unexpected costs or unexpected liabilities, including the risks and challenges associated with the Company's recent acquisition of Gen-Probe and operations in China; manufacturing risks, including the Company's reliance on a single or limited source of supply for key components, and the need to comply with especially high standards for the manufacture of many of its products; the Company's ability to predict accurately the demand for its products, and products under development, and to develop strategies to address its markets successfully; the early stage of market development for certain of the Company's products; the Company's leverage risks, including the Company's obligation to meet payment obligations and financial covenants associated with its debt; risks related to the use and protection of intellectual property; expenses, uncertainties and potential liabilities relating to litigation, including, without limitation, commercial, intellectual property, employment and product liability litigation; technical innovations that could render products marketed or under development by the Company obsolete; competition; the risks of conducting business internationally, including the effect of exchange rate fluctuations on those operations; and the Company's ability to attract and retain qualified personnel.

The risks included above are not exhaustive. Other factors that could adversely affect the combined company's business and prospects are described in the filings made by the Company with the SEC. The Company expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any such statements presented herein to reflect any change in expectations or any change in events, conditions or circumstances on which any such statements are based.

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