



## Rosetta Genomics Reports Third Quarter 2016 Financial Results

*Introduces 2017 Revenue and Unit Guidance for RosettaGX Reveal*

**PHILADELPHIA and REHOVOT, Israel (December 20, 2016)** – Rosetta Genomics Ltd. (NASDAQ: ROSG), a genomic diagnostics company that improves treatment decisions by providing timely and accurate diagnostic information to physicians, announces financial results for the three and nine months ended September 30, 2016.

### **Highlights for the third quarter of 2016 and recent weeks include:**

- Announced the publication of a clinical validation study in support of RosettaGX Reveal™ (Reveal), Rosetta's first-of-its-kind microRNA classifier for indeterminate thyroid nodules, in the peer-reviewed *Journal of Clinical Pathology*;
- Reveal was featured on the cover of the October issue of the peer-reviewed journal *Cancer Cytopathology*;
- Announced that Reveal is now available to be used on ThinPrep® samples and reported results from a study confirming that Reveal produces the same high level performance on ThinPrep prepared slides as it does on a direct smear from a thyroid Fine Needle Aspirate ("FNA") biopsy;
- Entered into an exclusive distribution agreement with Rhenium Ltd. for the sales and marketing of Reveal in Israel, where Clalit, (General Sick Fund), the largest organization and the first health insurance institution in Israel, has indicated it will include the Reveal assay in its Sick Fund;
- Closed concurrent registered direct and private placement offerings with one prominent institutional healthcare investor with expected net proceeds of approximately \$4.6 million;
- Entered into a research agreement with Sheba Medical Center at Tel HaShomer, Israel, to develop a microRNA-based signature to predict response to nivolumab, an immunotherapy drug marketed as Opdivo®, which is approved for the treatment of lung cancer; and
- Fortified its intellectual property portfolio with two new patent allowances for the company's novel microRNA platform technology as a prognostic for predicting progression of platinum-resistant stage III ovarian cancer and for diagnosing pleural mesothelioma or distinguishing between pleural mesothelioma and other cancers.

## Management Commentary

“Throughout 2016 we have been focused on the successful commercial launch of our Reveal assay for the classification of indeterminate thyroid nodules and we have made significant progress advancing this important product offering. We were pleased that two peer-reviewed journal articles supporting the clinical and analytical validation of Reveal were published in prestigious journals, which considerably enhances our sales and marketing efforts. In addition, we presented data from a study confirming that Reveal produces the same high-level performance on ThinPrep® prepared slides as it does on a direct smear from a thyroid Fine Needle Aspirate (FNA) biopsy. This opens our market to pathologists who prefer to use ThinPrep slides and we have since seen an uptick in demand,” stated Kenneth A. Berlin, President and Chief Executive Officer of Rosetta Genomics.

“We remain committed to advancing our strategy to use Reveal to access new accounts to promote our exceptional thyroid offering as well as our urologic cancer and solid tumor product lines. We believe that opening new relationships with Reveal will allow us to bring our solid tumor and urologic oncology offerings to many of these new accounts, thus further accelerating revenue growth.

“In addition to focusing on our suite of marketed diagnostic assays, we made significant progress on a number of important corporate initiatives that further strengthen Rosetta Genomics. We entered into a research collaboration to identify a microRNA-based biomarker to predict treatment response to Opdivo, fortified our microRNA intellectual property portfolio with two new patent allowances and strengthened our balance sheet by closing financing transactions with expected net proceeds of \$4.6 million.

“As we enter 2017, Rosetta Genomics is well-positioned for success and we look forward to achieving a series of value-creating milestones,” concluded Mr. Berlin.

## Third Quarter Financial Results

- Revenues for the third quarter of 2016 decreased 10% to \$2.2 million compared with \$2.4 million for the third quarter of 2015, primarily due to lower sales of urologic and solid tumor testing services as the Company refocused its sales force on the Reveal introduction.
- Revenues from urologic cancer testing services for the third quarter of 2016 was \$970,000, compared with \$1.3 million for the third quarter of 2015, and represented approximately 44% of clinical testing revenues for the third quarter of 2016.
- Revenues from solid tumor testing services for the third quarter of 2016 of \$841,000 decreased 26% compared with \$1.1 million in the third quarter of 2015, and represented 38% of total clinical testing revenues during the third quarter of 2016.
- Reveal revenues for the third quarter of 2016 were \$282,000, a 70% increase compared with \$166,000 for the second quarter of 2016. There were no Reveal revenues in 2015 as the assay was launched commercially in the first quarter of 2016. Reveal revenues represented 13% of total clinical testing revenues in the third quarter of 2016.

- The Company also had \$107,000 of revenues from Hematological FISH testing (HEME FISH), a new line of business this quarter, which represented 5% of total clinical testing revenues in the third quarter of 2016.
- On a non-GAAP basis, gross billings for Reveal during the third quarter of 2016 were \$930,000 compared with \$511,000 for the second quarter of 2016, representing growth of 82%. Gross billings are the aggregate amounts invoiced to customers.
- Cost of revenues for the third quarter of 2016 decreased to \$1.8 million from \$2.2 million for the third quarter of 2015.
- Research and development expenses for the third quarter of 2016 increased to \$879,000 from \$586,000 for the third quarter of 2015, primarily due to timing of acquisition of clinical samples.
- Sales, marketing and business development expenses were \$1.7 million for the third quarters of 2016 and 2015.
- General and administrative expenses for the third quarter of 2016 decreased to \$1.8 million compared with \$1.9 million for the same period in 2015 primarily due to financing-related expenses in 2015.
- The operating loss for the third quarter of 2016 was \$3.9 million, which included \$238,000 of non-cash stock-based compensation expense, compared with an operating loss of \$3.9 million for the third quarter of 2015, which included \$211,000 of non-cash stock-based compensation expense.
- The net loss for the third quarter of 2016 was \$4.0 million, or \$0.19 per ordinary share on 20.9 million weighted average shares outstanding, compared with a net loss for the third quarter of 2015 of \$3.9 million, or \$0.27 per ordinary share on 14.8 million weighted average shares outstanding.
- On a non-GAAP basis, excluding the 238,000 of non-cash stock-based compensation expense, the net loss for the third quarter of 2016 would have been \$3.7 million, or \$0.18 per ordinary share.
- For 2015, on a non-GAAP basis, excluding the 211,000 of non-cash stock-based compensation expense, the net loss for the third quarter of 2015 would have been \$3.7 million, or \$0.25 per ordinary share.

### **Nine Month Financial Results**

- Revenues for the first nine months of 2016 increased 53% to \$7.2 million compared with \$4.7 million for the first nine months of 2015. On a pro forma basis (as if the PersonalizeDx acquisition occurred on January 1, 2015 instead of the actual acquisition date of April 13, 2015), revenues for the first nine months of 2016 increased 9% compared with pro forma revenues of \$6.6 million for the first nine months of 2015.
- Cost of revenues for the nine-month period ended September 30, 2016 was \$5.4 million compared with \$4.4 million for the same period of 2015.
- Total operating expenses for the first nine months of 2016 of \$13.1 million compared with \$10.9 million for the first nine months of 2015, which included a gain of \$2.4 million on bargain purchase related to the acquisition of PersonalizeDx.
- The operating loss for the first nine months of 2016 was \$11.3 million, which included \$697,000 of non-cash stock-based compensation expense, compared with an operating loss for the first nine months of 2015 of \$10.6 million, which included \$755,000 of non-cash

stock-based compensation expense as well as a gain of \$2.4 million on bargain purchase related to the acquisition of PersonalizeDx.

- The net loss for the first nine months of 2016 was \$11.4 million, or \$0.55 per ordinary share on 20.8 million weighted average shares outstanding, compared with a net loss for the first nine months of 2015 of \$10.6 million, or \$0.76 per ordinary share.

### **Balance Sheet Highlights**

As of September 30, 2016, Rosetta Genomics had cash, cash equivalents, restricted cash and short-term bank deposits of \$6.1 million, compared with \$13.6 million as of December 31, 2015. The Company used approximately \$9.1 million in cash to fund operations during the first nine months of 2016, and collected approximately \$6.9 million in cash from its clinical testing services as well as \$1.6 million from a licensing deal signed in December 2015. Following the close of the quarter, Rosetta Genomics closed concurrent registered direct and private placement offerings with one institutional healthcare investor for expected net proceeds of approximately \$4.6 million. Rosetta Genomics believes that its current cash, together with its existing operating plan, which includes cost-reduction plan should it be unable to raise additional capital, should provide sufficient liquidity resources for the Company and its subsidiaries through the third quarter of 2017.

### **2017 Revenue and Unit Guidance for RosettaGX Reveal**

Rosetta Genomics also today introduces 2017 revenue and unit guidance for RosettaGX Reveal. For 2017, Rosetta Genomics expects Reveal revenue to be between \$4.0 million and \$5.0 million, and expects to process between 2,500 and 3,500 Reveal units throughout the year.

ThinPrep is a registered trademark of Hologic, Inc. and Opdivo® is a registered trademark of Bristol-Myers Squibb.

### **Use of Non-GAAP Financial Measures**

This press release contains certain non-GAAP financial measures. A "non-GAAP financial measure" refers to a numerical measure of historical or future financial performance, financial position or cash flows that excludes (or includes) amounts that are included in (or excluded from) the most directly comparable measure calculated and presented in accordance with GAAP in the financial statements. In this release, Rosetta provides non-GAAP gross billings, non-GAAP net loss and non-GAAP net loss per share data as additional information relating to its operating results. The presentation of this additional information is not meant to be considered in isolation or as a substitute for revenues, net loss or net loss per share prepared in accordance with GAAP.

Pursuant to the requirements of Regulation G promulgated by the SEC, the Company has provided a reconciliation of each non-GAAP financial measure used in this earnings release and related conference call or webcast to the most directly comparable financial measure prepared in accordance with GAAP. This reconciliation is presented in the tables below under the heading "Reconciliation of GAAP to Non-GAAP Consolidated Statement of Operation." Investors are encouraged to review these reconciliations to ensure they have a thorough understanding of the

reported non-GAAP financial measures and their most directly comparable GAAP financial measures.

Management uses these non-GAAP measures for internal reporting and forecasting purposes. The Company has provided these non-GAAP financial measures in addition to GAAP financial results because it believes that these non-GAAP financial measures provide useful information to certain investors and financial analysts for comparison across accounting periods not influenced by certain non-cash items that are not used by management when evaluating the Company's historical and prospective financial performance.

### **About Rosetta Genomics**

Rosetta is pioneering the field of molecular diagnostics by offering rapid and accurate diagnostic information that enables physicians to make more timely and informed treatment decisions to improve patient care. Rosetta has developed a portfolio of unique diagnostic solutions for oncologists, urologists, endocrinologists, cytopathologists and other specialists to help them deliver better care to their patients. RosettaGX Reveal™, a Thyroid microRNA Classifier for the diagnosis of cancer in thyroid nodules, as well as the full RosettaGX™ portfolio of cancer testing services are commercially available through the Company's Philadelphia, PA- and Lake Forest, CA-based CAP-accredited, CLIA-certified labs.

### **Forward-Looking Statement Disclaimer**

Various statements in this release, including but not limited to, statements relating to accelerating revenue growth and the 2017 revenue and unit guidance for Reveal constitute forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by these forward-looking statements as a result of various important factors, including those risks more fully discussed in the "Risk Factors" section of Rosetta's most recently filed Annual Report on Form 20-F, as filed with the SEC. In addition, any forward-looking statements represent Rosetta's views only as of the date of this release and should not be relied upon as representing its views as of any subsequent date. Rosetta does not assume any obligation to update any forward-looking statements unless required by law.

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Tables to Follow

**CONDENSED INTERIM CONSOLIDATED BALANCE SHEETS**

U.S. dollars in thousands

	<u>September 30,</u> <b>2016</b>	<u>December 31,</u> <b>2015</b>
	<u>Unaudited</u>	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 5,423	\$ 12,447
Short-term bank deposits and restricted cash	602	1,098
Trade receivables	3,146	3,633
Other accounts receivable and prepaid expenses	<u>605</u>	<u>2,192</u>
<u>Total</u> current assets	<u>9,776</u>	<u>19,370</u>
LONG TERM ASSETS:		
Property and equipment, net	2,767	2,975
Restricted bank deposit and other long-term receivables	<u>84</u>	<u>78</u>
<u>Total</u> long term assets	<u>2,851</u>	<u>3,053</u>
<u>Total</u> assets	<u>\$ 12,627</u>	<u>\$ 22,423</u>

## CONDENSED INTERIM CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands (except share data)

	<u>September 30, 2016</u>	<u>December 31, 2015</u>
	<u>Unaudited</u>	
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current maturities of capital lease	\$ 55	\$ -
Trade payables	1,196	1,070
Other accounts payables and accruals	2,376	1,733
<u>Total current liabilities</u>	<u>3,627</u>	<u>2,803</u>
LONG-TERM LIABILITIES:		
Obligation under capital lease	79	-
<u>Total long-term liabilities</u>	<u>79</u>	<u>-</u>
COMMITMENTS AND CONTINGENT LIABILITIES		
SHAREHOLDERS EQUITY:		
Share capital:		
Ordinary Shares of NIS 0.6 par value: 60,000,000 shares authorized at September 30, 2016 and December 31, 2015; 20,870,513 and 20,518,794 shares issued at September 30, 2015 and December 31, 2015, respectively; 20,870,513 (unaudited) and 20,515,536 shares outstanding at September 30, 2016 and December 31, 2015, respectively	3,247	3,194
Additional paid-in capital	157,340	156,696
Accumulated deficit	(151,666)	(140,270)
<u>Total shareholders' equity</u>	<u>8,921</u>	<u>19,620</u>
<u>Total liabilities and shareholders' equity</u>	<u>\$ 12,627</u>	<u>\$ 22,423</u>

## CONSOLIDATED STATEMENTS OF OPERATIONS

U.S. dollars in thousands (except share and per share data)

	Nine months ended September 30,		Three months ended September 30,	
	2016	2015	2016	2015
	Unaudited		Unaudited	
Revenues	\$ 7,215	\$ 4,709	\$ 2,200	\$ 2,431
Cost of revenues:	5,437	4,437	1,790	2,168
Gross profit (loss)	1,778	272	410	263
Operating expenses:				
Research and development, net	2,338	1,947	879	586
Marketing and business development	5,319	5,753	1,680	1,678
General and administrative	5,455	5,525	1,791	1,882
Gain from bargain purchase related to acquisition of CynoGen, Inc.	-	(2,352)	-	-
Total operating expenses	13,112	10,873	4,350	4,146
Operating loss	11,334	10,601	3,940	3,883
Financial expense (income), net	40	6	16	47
Tax expenses	22	15	10	5
Net loss	\$ 11,396	\$ 10,622	\$ 3,966	\$ 3,935
Basic and diluted net loss per ordinary share attributable to Rosetta Genomics' shareholders	\$ 0.55	\$ 0.76	\$ 0.19	\$ 0.27
Weighted average number of ordinary shares used to compute basic and diluted net loss per ordinary share	20,794,330	13,991,549	20,863,018	14,765,423

USD in thousands

Revenues for Reveal  
Unrecognized billings  
Gross billings for Reveal

Quarter ended	
September 30, 2016	June 30, 2016
\$ 282	\$ 166
648	345
\$ 930	\$ 511

USD in thousands

Net loss  
Share-based compensation  
**non-GAAP net loss**

Quarter ended	
September 30,	
2016	2015
(Unaudited)	(Unaudited)
\$ 3,966	\$ 3,935
238	211
<b>\$ 3,728</b>	<b>\$ 3,724</b>

Basic and diluted per share data

Net loss  
Share-based compensation  
**non-GAAP net loss**

Quarter ended	
September 30,	
2016	2015
(Unaudited)	(Unaudited)
\$ 0.19	\$ 0.27
\$ 0.01	\$ 0.01
<b>\$ 0.18</b>	<b>\$ 0.25</b>

Weighted average number of Ordinary shares used to  
compute basic and diluted net loss per Ordinary share

20,863,018 14,765,423

USD in thousands

GAAP revenues  
Additional revenues from PersonalizedDx for the non-consolidated period of  
January 1, 2015 - April 12, 2015  
Pro forma revenues

Nine months ended	
September 30, 2015	
(Unaudited)	
\$ 4,709	
1,903	
\$ 6,612	

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