February 19, 2013

RedHill Biopharma Reports 2012 Fourth Quarter and Year-End Results

Key Planned Milestones for 2013 Include Commencement of Phase III and Phase II/III Studies With RHB-104 (Crohn's Disease) and RHB-105 (*H. pylori*), Respectively, and New Drug Application (NDA) Filings With RHB-102 (Oncology Support Antiemetic) and RHB-103 (Acute Migraine)

TEL-AVIV, Israel, Feb. 19, 2013 (GLOBE NEWSWIRE) -- **RedHill Biopharma Ltd.** (Nasdaq:RDHL) (TASE:RDHL), an Israeli biopharmaceutical company focused primarily on the acquisition and development of late clinical-stage, patent-protected, new formulations and combinations of existing drugs, released its financial results for the fourth quarter and year ended December 31, 2012.

2012 was characterized by significant milestones for the Company, including:

(i) Positive results in a pivotal comparative bioequivalence clinical trial with RHB-102, a proprietary once-daily formulation of a leading oncology support drug for the prevention of nausea and vomiting,

(ii) Positive results in a pivotal bioequivalence clinical trial and a successful pre-NDA meeting with the FDA with RHB-103, a proprietary oral thin film formulation of a leading drug for the treatment of acute migraine,

(iii) Filing of a new U.S. composition patent covering RHB-104 (Crohn's disease) through 2029, and

(iv) NASDAQ (ADR) listing in December 2012.

Financial highlights for the year ended December 31, 2012:

Research and Development Expenses for the year ended December 31, 2012 were approximately $6.5 million, an increase of $1.1 million (approximately 20%), compared to $5.4 million in the previous year. This increase was mainly attributed to the clinical trials conducted with RHB-102 and RHB-103 and advanced clinical trial preparations with RHB-104 and RHB-105.

General and Administrative Expenses for the year ended December 31, 2012 were approximately $2.6 million, an increase of $0.1 million (approximately 4%) compared to $2.5 million in the previous year. This increase was due in part to an increase in professional service fees in connection with the NASDAQ listing, partly offset by a decrease in share based payments.

Operating Loss for the year ended December 31, 2012 was approximately $9.0 million, an increase of $1.1 million (approximately 14%) compared to $7.9 million in the previous year. This increase was due in part to an increase in research and development expenses.

Financing Expenses (net) for the year ended December 31, 2012 were approximately $1.3 million, a decrease of $6.3 million (approximately 83%), compared to $7.6 million in the previous year. This decrease was mainly due to a non-cash financing expense of $7.9 million resulting from the conversion of mandatory convertible loans into equity prior to the 2011 IPO in Tel-Aviv, compared to non-cash expenses of $1.5 million resulting from the acquisition of royalty obligations from investors in 2012.

Net Cash Used in Operating Activities was $6.8 million for the year ended December 31, 2012, an increase of $2.1 million (approximately 47%), compared to $4.7 million in the previous year. This increase was mainly due to the clinical trials and clinical trial preparations referred to above and increased professional services expenses.

Net Cash Resulting from Investment Activities was $3.0 million for the year ended December 31, 2012, compared to cash used for investment activities of $4.8 million in the previous year. The change was mainly due to long term investments during 2011 which became short term investments (with a term of less than three months) during 2012.

Cash Balance[1] on December 31, 2012 was approximately $16.8 million, an increase of $2.7 million (or 19%), compared to a cash balance of $14.1 million in the previous year. This increase was mainly due to a November 2012 private placement of approximately $6.5 million, offset largely by the cash used in operating activities.

[1] Including cash, bank deposits and short term investments.

Key operational highlights for the year ended December 31, 2012:

1. In April 2012, the Company reported positive results in a pivotal comparative bioequivalence trial with RHB-102, a once-daily oral formulation of ondansetron for the prevention of nausea and vomiting in cancer patients.

2. In August 2012, the Company and its Canadian co-development partner IntelGenx Corp. announced positive results in a pivotal bioequivalence clinical trial with RHB-103, an oral thin-film rizatriptan for the treatment of migraine. On November 7, 2012, the Company and IntelGenx concluded a pre-New Drug Application (pre-NDA) meeting with the FDA related to RHB-103 and, given the positive outcome of the pre-NDA meeting, the Company estimates that an NDA will be filed during the first quarter of 2013.

3. In October 2012, the Company reported that as a result of discussions held with the FDA regarding the Company's IND (Investigational New Drug) amendment with RHB-104, for the treatment of Crohn's disease, there were no regulatory restrictions to commence a clinical trial. As of January 2013, a multi-site initiation process is underway in the U.S., Canada and Israel for a first multi-center, randomized, double-blind, placebo-controlled, parallel group initial Phase III study (the MAP US Study) to assess the efficacy and safety of fixed-dose combination RHB-104 in subjects with moderately to severely active Crohn's disease. The MAP US Study patient recruitment is planned to commence in the second quarter of 2013.

4. In October 2012, the Company reported advanced preparations for a Phase II/III clinical trial in the U.S. and Canada with RHB-105 for the treatment of *H. pylori* bacterial infection. The clinical trial is designed to test the safety and efficacy of RHB-105 in eradication of *H. pylori* bacteria which have been implicated in causing ulcers and are associated with gastric cancer. Subject to regulatory discussions and other preparations, the trial is expected to commence in the second quarter of 2013.

5. In October 2012, the Company entered into a term sheet with SCOLR Pharma, Inc. (OTCBB:SCLR) under which, subject to a definitive agreement, necessary corporate approvals and successful completion of due diligence, the Company will acquire exclusive, world-wide rights to two patent-protected 12 hour extended release drugs (based on SCOLR's patent-protected CDT® controlled release technology) in advanced stages of clinical development. The first drug is ibuprofen, an analgesic for the treatment of pain and inflammation. The second drug is pseudoephedrine, a decongestant for the treatment of cough and cold.

6. In October 2012, the Company reported positive results in three Multiple Sclerosis (MS) pre-clinical studies using the experimental autoimmune encephalomyelitis (EAE) model and is in advanced preparations for a Phase IIa proof of concept clinical trial in Israel to assess the efficacy and safety of its fixed dose oral drug combination, RHB-104, as an add-on therapy in patients treated for Relapsing Remitting MS. The Phase IIa clinical trial is expected to commence in the first quarter of 2013.

7. In January 2013, the United States Patent and Trademark Office (USPTO) issued a new patent for "Methods and Compositions for Treating Inflammatory Bowel Disease" expiring no earlier than in 2029, for RHB-104, intended primarily for the treatment of Crohn's disease.

8. As of December, 2012, the Company had received a total of approximately $6.5 million in connection with a private placement of shares and warrants, increasing its cash balance to approximately $18.5 million.

9. On December 27, 2012, the Company listed its ADS for trading on NASDAQ. Following the NASDAQ listing, the Company's securities are traded both on NASDAQ and on the Tel-Aviv Stock Exchange (TASE). The Bank of New York Mellon was appointed as the Company's depository bank. Each ADS represents 10 ordinary shares of the Company.

Ori Shilo, Deputy CEO Finance and Operations said: "As a result of the significant progress made by the Company in 2012, we are preparing marketing approval applications (NDA) for RHB-102 for the prevention of nausea and vomiting in cancer patients and for RHB-103 for the treatment of migraine, in parallel with commercialization efforts with potential partners. We completed our NASDAQ listing which provides us exposure to the U.S. financial markets and successfully completed a pre-listing private financing of approximately $6.5 million. Our cash position remains strong with $18.5 million at the end of the year and no debt. The strong balance sheet is expected to allow us to execute our plans in 2013, including the commencement of the Phase III MAP US Study with RHB-104 for Crohn's disease and a Phase II/III trial with RHB-105 for *H. pylori* bacteria causing ulcers."

Conference Call and Webcast Information:

The Company will host a conference call and an audio webcast at 09:00am EST on Wednesday, February 20, 2013.

To participate in the conference call please dial 1-866-966-9439 (domestic U.S., toll free) or +1-631-510-7498 (International) and use access code: 11015754 #.

The conference call will be broadcasted simultaneously and archived on the Company's website, http://ir.redhillbio.com/. To participate, please access the Company's website at least 15 minutes ahead of the conference to register, download, and install any necessary audio software. The webcast replay will be available on RedHill's website for 30 days.

About RedHill Biopharma Ltd.:

RedHill Biopharma is an emerging Israeli biopharmaceutical company focused primarily on the acquisition and development of late clinical-stage, patent protected, new formulations and combinations of existing drugs. The Company's current product pipeline includes a once-daily formulation of a leading congestive heart failure and high blood pressure drug, a once-daily formulation of a leading chemotherapy and radiotherapy-induced nausea and vomiting prevention drug, an oral thin film formulation drug for the treatment of acute migraine, a combination therapy for the treatment of Crohn's disease as well as Multiple Sclerosis (MS) disease, a combination therapy for the treatment of *Helicobacter pylori* bacteria causing ulcers, and an encapsulated formulation for bowel preparation ahead of certain gastro procedures. For more information please visit: www.redhillbio.com.

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements may be preceded by the words "intends," "may," "will," "plans," "expects," "anticipates," "projects," "predicts," "estimates," "aims," "believes," "hopes," "potential" or similar words. Forward-looking statements are not guarantees of future performance, are based on certain assumptions and the Company's current and best understanding of the regulatory status and are subject to various known and unknown risks and uncertainties, many of which are beyond the Company's control, and cannot be predicted or quantified and consequently, actual results may differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, without limitation, risks and uncertainties associated with (i) the initiation, timing, progress and results of the Company's preclinical studies, clinical trials, and other therapeutic candidate development efforts; (ii) the Company's ability to advance its therapeutic candidates into clinical trials or to successfully complete its preclinical studies or clinical trials; (iii) the extent and number of additional studies that the Company may be required to conduct and the Company's receipt of regulatory approvals for its therapeutic candidates, and the timing of other regulatory filings and approvals; (iv) the clinical development, commercialization, and market acceptance of the Company's therapeutic candidates; (v) the Company's ability to establish and maintain corporate collaborations; (vi) the interpretation of the properties and characteristics of the Company's therapeutic candidates and of the results obtained with its therapeutic candidates in preclinical studies or clinical trials; (vii) the implementation of the Company's business model, strategic plans for its business and therapeutic candidates; (viii) the scope of protection the Company is able to establish and maintain for intellectual property rights covering its therapeutic candidates and its ability to operate its business without infringing the intellectual property rights of others; (ix) estimates of the Company's expenses, future revenues capital requirements and the Company's needs for additional financing; (x) competitive companies, technologies and the Company's industry; and (xi) statements as to the impact of the political and security situation in Israel on the Company's business. More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements is set forth in the Company's filings with the Securities and Exchange Commission (SEC), including the Company's Registration Statement on From 20-F filed with the SEC on December 26, 2012, and its Reports on Form 6-K. Investors and security holders are urged to read these documents free of charge on the SEC's web site at http://www.sec.gov. All forward-looking statements included in this Press Release are made only as of the date of this Press Release. We assume no obligation to update any written or oral forward-looking statement made by us or on our behalf as a result of new information, future events or other factors.

REDHILL BIOPHARMA LTD.

STATEMENTS OF COMPREHENSIVE LOSS

	Year ended December 31	
	2012	**2011**
	U.S. dollars in thousands	
REVENUE	16	23
RESEARCH AND DEVELOPMENT EXPENSES	(6,455)	(5,414)
GENERAL AND ADMINISTRATIVE EXPENSES	(2,601)	(2,482)
OTHER EXPENSES	--	--
OPERATING LOSS	(9,040)	(7,873)
FINANCIAL INCOME	197	570
FINANCIAL EXPENSES	(1,483)	(8,200)
FINANCIAL EXPENSES NET	(1,286)	(7,630)

LOSS AND COMPREHENSIVE LOSS	(10,326)	(15,503)
LOSS PER ORDINARY SHARE — basic and diluted	(0.20)	(0.32)

REDHILL BIOPHARMA LTD.

STATEMENTS OF FINANCIAL POSITION

	December 31	
	2012	**2011**
	U.S. dollars in thousands	
CURRENT ASSETS:		
Cash and cash equivalents	16,814	14,070
Bank deposits	486	3,013
Financial assets at fair value through profit or loss	1,065	1,564
Prepaid expenses and receivables	198	89
	18,563	18,736
NON-CURRENT ASSETS:		
Restricted bank deposit	75	73
Fixed assets	113	132
Intangible assets	1,345	1,245
	1,533	1,450
Total assets	20,096	20,186
CURRENT LIABILITIES --		
Accounts payable and accrued expenses	1,078	513
NON-CURRENT LIABILITIES:		
Royalty obligations to investors	--	886
Total liabilities	1,078	1,399
COMMITMENTS		
EQUITY:		
Ordinary shares	143	142
Ordinary shares to be issued	8,020	--
Additional paid-in capital	31,469	31,168
Warrants	3,273	2,686
Accumulated deficit	(23,887)	(15,209)
Total equity	19,018	18,787
Total liabilities and equity	20,096	20,186

REDHILL BIOPHARMA LTD.

STATEMENTS OF CASH FLOWS

	Year ended December 31	
	2012	2011
	U.S. dollars in thousands	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Loss	(10,326)	(15,503)
Adjustments in respect of income and expenses not involving cash flows:		
Share-based compensation to employees and service providers	1,648	2,863
Fair value losses on mandatory convertible loans	--	7,938
Depreciation	24	15
Fair value losses (gains) on financial assets at fair value through profit or loss	(57)	29
Revaluation of bank deposits	(4)	9
Accretion and settlement of royalty obligations to investors	1,473	168
Exchange differences in respect of cash and cash equivalents	(12)	(640)
Changes in asset and liability items:		
Decrease (increase) in prepaid expenses and receivables	(109)	61
Increase in accounts payable and accrued expenses	568	369
Net cash used in operating activities	(6,795)	(4,691)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of fixed assets	(8)	(136)
Purchase of intangible assets	(100)	(45)
Changes in investment in bank deposits	2,529	(3,080)
Acquisition of financial assets at fair value through profit or loss	(1,032)	(1,506)
Proceeds from sale of financial assets at fair value through profit or loss	1,588	--
Net cash used in investing activities	2,977	(4,767)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds on account of shares and warrants, net	6,248	--
Proceeds from issuance of shares and warrants under February 2, 2011 prospectus, net of issuance expenses	--	12,662
Exercise of warrants and options into shares, net of expenses	302	1,176
Proceeds from mandatory convertible loans and royalty obligations to investors	--	--
Net cash provided by financing activities	6,550	13,838
INCREASE IN CASH AND CASH EQUIVALENTS	2,732	4,380
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	12	640
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR	14,070	9,050
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF YEAR	16,814	14,070
Supplementary information on interest received in cash	126	14
Supplementary Information on financing activities not involving cash flows :		
Settlement of the royalty obligations	2,359	--
Conversion of mandatory convertible loans	--	19,183

CONTACT: IR contact (US):

Lauren Glaser

Vice President

The Trout Group

+1-646-378-2972

lglaser@troutgroup.com

Company contact:

Adi Frish

Senior VP Business Development & Licensing

RedHill Biopharma

+972-54-6543-112

adi@redhillbio.com

Source: RedHill Biopharma Ltd.