February 26, 2015

RedHill Biopharma Reports 2014 Fourth Quarter and Year-End Financial Results

Key Highlights Include:

- **Strong cash position of over $34 million, following completion of a $14.4 million U.S. public offering in February 2015**
- **With three ongoing Phase III clinical studies for gastrointestinal diseases, R&D expenses increased to $12.7 million in 2014 compared to $8.1 million in 2013**
- **Anticipated 2015 milestones include top-line data from the ongoing Phase III study of RHB-105 for the treatment of *H. pylori* bacterial infection, expected in Q2/2015, and from the ongoing Phase III study of BEKINDA™ (RHB-102) for acute gastroenteritis and gastritis, expected in Q4/2015**

TEL-AVIV, Israel, Feb. 26, 2015 (GLOBE NEWSWIRE) -- RedHill Biopharma Ltd. (Nasdaq:RDHL) (TASE:RDHL) ("RedHill" or the "Company"), an Israeli biopharmaceutical company primarily focused on late clinical-stage, proprietary, orally-administered drugs for inflammatory and gastrointestinal diseases, including gastrointestinal cancers, today reported its financial results for the year ended December 31, 2014.

Financial highlights for the year ended December 31, 2014 and for the fourth quarter of 2014:

Revenues for the year ended December 31, 2014 were $7.0 million, compared to immaterial revenues for the year ended December 31, 2013. The revenues in 2014 were mainly from an upfront payment of $7.0 million received from Salix Pharmaceuticals, Inc. ("Salix") for the out-licensing of RedHill's RHB-106 encapsulated bowel preparation and related rights.

Cost of Revenues for the year ended December 31, 2014 was $1.0 million compared to immaterial Cost of Revenues in the year ended December 31, 2013. The Cost of Revenues resulted primarily from a payment made to Giaconda Limited under a 2010 Asset Purchase Agreement, triggered by the payment received from Salix as part of the out-licensing transaction described above.

Research and Development Expenses for the year ended December 31, 2014 were approximately $12.7 million, an increase of $4.6 million, or approximately 57%, compared to $8.1 million for the year ended December 31, 2013. The increase resulted primarily from clinical trial costs of approximately $3.5 million, net, related mainly to the ongoing Phase III clinical studies of RHB-104 (Crohn's disease), RHB-105 (*H. pylori*) and BEKINDA™ (gastroenteritis and gastritis). Research and Development Expenses for the quarter ended December 31, 2014 were approximately $3.7 million, compared to $2.6 million in the comparable quarter of 2013. The increase was mainly due to the RHB-104, RHB-105 and BEKINDA™ Phase III programs.

General and Administrative Expenses for the year ended December 31, 2014 were approximately $4.0 million, an increase of $1.3 million, or approximately 48%, compared to $2.7 million for the year ended December 31, 2013. The increase resulted primarily from an increase in payroll and related expenses as a result of the recruitment of new employees and an increase in share-based payments and professional services. General and Administrative Expenses for the quarter ended December 31, 2014 were approximately $1.1 million compared to $0.9 million in the comparable quarter of 2013. The increase was mainly due to an increase in professional services.

Operating Loss for the year ended December 31, 2014 was approximately $10.6 million compared to $10.8 million for the year ended December 31, 2013. The decrease was mainly due to revenues from the Salix licensing transaction, partially offset by an increase in Research and Development Expenses. Operating Loss for the quarter ended December 31, 2014 was $4.8 million, compared to $3.5 million in the comparable quarter of 2013. The increase in the fourth quarter of 2014 was mainly due to an increase in Research and Development Expenses.

Net Cash Used in Operating Activities for the year ended December 31, 2014 was approximately $12.2 million, an increase of $3.8 million, or approximately 45%, compared to $8.4 million for the year ended December 31, 2013. The increase was a direct result of an increase in operations, mainly an increase in advanced payments to suppliers and a decrease in accounts payable, both mainly related to research and development activities. The increase was partially offset by revenues from the Salix transaction. Net Cash Used in Operating Activities for the quarter ended December 31, 2014 was $5.9 million, compared to $2.5 million in the comparable quarter of 2013. The increase was mainly due to an increase in advance payments to suppliers and a decrease in accounts payable, both related to research and development activities.

Net Cash Used in Investment Activities for the year ended December 31, 2014 was approximately $17.9 million, compared to Net Cash Resulting from Investment Activities of $1.1 million for the year ended December 31, 2013. The increase was mainly due to investments in bank deposits and an upfront payment of $1.0 million to WILEX AG for the acquisition of rights to the oncology drug MESUPRON®.

Cash Resulting from Financing Activities for the year ended December 31, 2014 was approximately $24.4 million, compared to $2.3 million for the year ended December 31, 2013. The Cash Resulting from Financing Activities in 2014 resulted primarily from the two financing rounds in January 2014, in the U.S. and Israel, whereas in 2013 it resulted primarily from the exercise of warrants.

Cash Balance[1] as of December 31, 2014 was approximately $22.9 million, an increase of $10.8 million, or approximately 89%, compared to $12.1 million as of December 31, 2013 and a decrease of $6.1 million, approximately 21%, compared to $29 million as of September 30, 2014. As of February 25, 2015, following the closing of the underwritten public offering, RedHill had cash and short term investments of approximately $34.6 million.

Ori Shilo, Deputy CEO, Finance and Operations said: "We reached a number of significant milestones in 2014, including the out-licensing to Salix Pharmaceuticals of the rights to the bowel preparation drug RHB-106 which generated $7.0 million from an upfront payment. RedHill has also made substantial clinical development progress throughout 2014 and is currently conducting three Phase III clinical studies for gastrointestinal diseases with top-line Phase III data expected from two of these studies during 2015. We recently secured gross proceeds of approximately $14.4 million through our first public offering in the U.S., in which prominent investors participated, bringing our cash balance to over $34 million as of February 25, 2015. Our strong cash position, together with the continuing support from our shareholders, allows us to continue to pursue our clinical and business development plans in 2015."

Selected operational highlights for the year ended December 31, 2014 and anticipated key milestones for 2015:

RHB-105 for *H. pylori* bacterial infection

- **Q2/2015** - Top-line data expected from the Phase III study with RHB-105, currently ongoing in the U.S. (the ERADICATE Hp study).

In November 2014, the U.S Food and Drug Administration (FDA) designated RHB-105 as a Qualified Infectious Disease Product (QIDP) under the FDA's Generating Antibiotic Incentives Now (GAIN) Act. This designation allows for an additional five years of market exclusivity, Fast-Track status (an expedited development pathway) and Priority Review status (shortened review time for marketing applications). In addition, RedHill is pursuing a significantly broader indication with RHB-105 than existing treatments by targeting *H. pylori* infection as a first line treatment regardless of ulcer status.

BEKINDA™ (RHB-102) - for gastroenteritis and gastritis, and for chemotherapy and radiotherapy-induced nausea and vomiting

- **Q4/2015** - Top-line data expected from the Phase III study for acute gastroenteritis and gastritis (the GUARD study), currently ongoing in the U.S.

In December 2014, the Company announced that the first patients had been enrolled in the GUARD study. The randomized, double-blind, placebo-controlled, parallel group Phase III study is being conducted in the U.S. with a planned enrollment of 320 adults and children over the age of 12 who suffer from acute gastroenteritis and gastritis.

RedHill submitted, in December 2014, a European Marketing Authorization Application (MAA) to the UK Medicines and Healthcare Products Regulatory Agency (MHRA), seeking European marketing approval of BEKINDA™ for the prevention of chemotherapy and radiotherapy-induced nausea and vomiting (CINV and RINV, respectively). The MAA was validated by the MHRA and RedHill expects to receive feedback regarding the MAA during the second half of 2015. RedHill is also pursuing marketing approval of BEKINDA™ in the U.S. for CINV prevention. Following a pre-NDA with the FDA, and in light of the FDA's feedback, RedHill intends to use post-marketing data, along with data generated from prior studies, to further support a potential New Drug Application (NDA) in the U.S.

RHB-104 - for Crohn's disease and other inflammatory diseases

- **Q2/2015** - Expected announcement of planned timelines for the interim analysis by the independent DSMB (Data Safety and Monitoring Board) and for the completion of the ongoing first Phase III study with RHB-104 for the treatment of Crohn's disease (the MAP US study).
- **H2/2015** - Top-line interim results expected from the ongoing Phase IIa proof of concept study with RHB-104 for the treatment of multiple sclerosis (MS) (the CEASE-MS study).

A protocol amendment was filed with the FDA in relation to the ongoing Phase III MAP US study, which included the inclusion of Crohn's disease patients with moderate to severe disease despite current treatment with anti-Tumor Necrosis Factor (anti-TNF) therapies infliximab (Remicade®) and adalimumab (Humira®), thus significantly increasing the number of Crohn's disease patients potentially eligible to enroll in the study. RedHill also reported its plan to increase the number of clinical sites in the study, currently being conducted in the U.S., Canada and Israel, from 100 to 120, by adding new sites in Australia, New Zealand and Europe.

RHB-106 - **encapsulated bowel cleanser**

- **Q2-Q3/2015** - Planned initiation of a clinical study by Salix Pharmaceuticals, Inc.

In February 2014, RedHill and Salix entered into an exclusive worldwide license agreement for RHB-106 and other purgative developments. RedHill received an upfront payment of $7.0 million and Salix agreed to pay an additional $5.0 million in subsequent potential milestone payments to RedHill, as well as tiered royalties on net sales ranging from low single digits up to low double digits. Salix publicly estimated its encapsulated bowel prep prescription share outlook at 20% of the market and annual revenues of $280 million (peak year).

Conference Call and Webcast Information:

The Company will host a conference call on Thursday, February 26, 2015, at 9:00 am EST to review the financial results and business highlights.

To participate in the conference call, please dial the following numbers five to ten minutes prior to the start of the call: **United States: +1-646-254-3365; international: +1-877-280-2296; and Israel: +972-3-721-9510. The access code for the call is 2279503**.

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

About RedHill Biopharma Ltd.:

RedHill Biopharma Ltd. (Nasdaq:RDHL) (TASE:RDHL) is an emerging Israeli biopharmaceutical company focused on the development and acquisition of late clinical-stage, proprietary, orally-administered drugs for the treatment of inflammatory and gastrointestinal diseases, including gastrointestinal cancers. RedHill's current pipeline of proprietary products includes: (i) **RHB-105 -** an oral combination therapy for the treatment of *Helicobacter pylori* infection, with an ongoing first Phase III study; (ii) **RHB-104 -** an oral combination therapy for the treatment of Crohn's disease, with an ongoing first Phase III study; (iii) **BEKINDA™ (RHB-102) -** a once-daily oral pill formulation of ondansetron with a Phase III study in the U.S. for acute gastroenteritis and gastritis and a European marketing application for chemotherapy and radiotherapy-induced nausea and vomiting submitted in December 2014; (iv) **RHB-106 -** an encapsulated formulation for bowel preparation licensed to Salix Pharmaceuticals, Ltd.; (v) **MESUPRON® -** a Phase II-stage uPA inhibitor, administered by oral capsule, targeting gastrointestinal and other solid tumor cancers; (vi) **RP101 -** currently subject to an option-to-acquire by RedHill, RP101 is a Phase II-stage Hsp27 inhibitor, administered by oral tablet, targeting pancreatic and other gastrointestinal cancers; (vii) **RIZAPORT™ (RHB-103) -** an oral thin film formulation of rizatriptan for acute migraines with a U.S. NDA currently under discussions with the FDA and a European marketing application submitted in October 2014; and (viii) **RHB-101 -** a once-daily oral pill formulation of the cardio drug carvedilol.

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 based on certain assumptions 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, approvals and feedback; (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) parties from whom the Company licenses its intellectual property defaulting in their obligations to the Company; (x) estimates of the Company's expenses, future revenues capital requirements and the Company's needs for additional financing; and (xi) competitive companies and technologies within the Company's industry. 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 Annual Report on Form 20-F filed with the SEC on February 25, 2014. 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 unless required by law.

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

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REDHILL BIOPHARMA LTD.

CONDENSED INTERIM STATEMENTS OF COMPREHENSIVE LOSS

	Year ended December 31		Three months ended December 31	
	2014	2013	2014	2013
	U.S. dollars in thousands			
REVENUES				
Licensing revenue	7,000	--	--	--
Other revenue	14	12	1	1
TOTAL REVENUES	7,014	12	--	1
COST OF REVENUE	1,050	--	--	--
RESEARCH AND DEVELOPMENT EXPENSES, NET	12,700	8,100	3,704	2,565
GENERAL AND ADMINISTRATIVE EXPENSES	4,011	2,684	1,111	916
OTHER INCOME	100	--	--	--
OPERATING LOSS	10,647	10,772	4,804	3,480
FINANCIAL INCOME	319	158	--	45
FINANCIAL EXPENSES	383	14	514	5
FINANCIAL INCOME (EXPENSES), NET	(64)	144	(514)	40
LOSS AND COMPREHENSIVE LOSS	10,711	10,628	5,328	3,440
LOSS PER ORDINARY SHARE (U.S. dollars)				
Basic	0.12	0.17	0.06	0.05
Diluted	0.13	0.17	0.06	0.05
WEIGHTED AVERAGE OF ORDINARY SHARES				
used in computing basic loss per ordinary share (in thousands)	86,610	62,379	87,884	64,099

used in computing diluted loss per share (in thousands)	87,222	62,379	87,605	64,099

REDHILL BIOPHARMA LTD.

CONDENSED INTERIM STATEMENTS OF FINANCIAL POSITION

	December 31	
	2014	**2013**
	U.S. dollars in thousands	
CURRENT ASSETS:		
Cash and cash equivalents	5,892	11,851
Bank deposits	17,053	19
Financial assets at fair value through profit or loss	--	243
Prepaid expenses and receivables	3,074	488
	26,019	12,601
NON-CURRENT ASSETS:		
Bank deposits	76	81
Fixed assets	146	103
Intangible assets	2,615	1,555
	2,837	1,739
T O T A L ASSETS	28,856	14,340
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	1,720	2,415
NON-CURRENT LIABILITIES:		
Derivative financial instruments	2,125	--
T O T A L LIABILITIES	3,845	2,415
COMMITMENTS		
EQUITY:		
Ordinary shares	240	174
Additional paid-in capital	65,461	43,144
Warrants	1,528	1,867
Accumulated deficit	(42,218)	(33,260)
T O T A L EQUITY	25,011	11,925
T O T A L LIABILITIES AND EQUITY	28,856	14,340

REDHILL BIOPHARMA LTD.

CONDENSED INTERIM STATEMENTS OF CASH FLOWS

	Year ended December 31		Three months ended December 31	
	2014	**2013**	**2014**	**2013**
	U.S. dollars in thousands			
CASH FLOW FROM OPERATING ACTIVITIES:				
Loss	(10,711)	(10,628)	(5,328)	(3,440)
Adjustments in respect of income and expenses not involving cash flow:				

Share-based compensation to employees and service providers	1,753	1,255	400	238
Fair value gain on derivative financial instruments	(200)	--	359	--
Depreciation	27	24	8	6
Cost of out-licensing of intangible assets	50	--	--	--
Fair value gains on financial assets at fair value through profit or loss	--	(54)	--	(4)
Revaluation of bank deposits	(29)	(16)	(9)	(3)
Exchange differences relating to cash and cash equivalents	237	(64)	128	(32)
	1,838	1,145	886	205
Changes in assets and liability items:				
Increase in prepaid expenses and receivables	(2,586)	(290)	(556)	(290)
Increase (decrease) in accounts payable and accrued expenses	(770)	1,337	(939)	491
	(3,356)	1,047	(1,495)	781
Net cash used in operating activities	(12,229)	(8,436)	(5,937)	(2,454)
CASH FLOW FROM INVESTING ACTIVITIES:				
Purchase of fixed assets	(70)	(14)	(36)	(2)
Purchase of intangible assets	(1,035)	(210)	(15)	(10)
Change in investment in bank deposits	(7,000)	477	--	284
Investment in non-current bank deposits	(10,000)		--	
Proceeds from sale of financial assets at fair value through profit or loss	243	876	--	--
Net cash provided by (used in) investing activities	(17,862)	1,129	(51)	272
CASH FLOW FROM FINANCING ACTIVITIES:				
Proceeds from issuance of ordinary shares, warrants and derivative financial instruments, net	19,364	100	--	--
Exercise of warrants and options into shares, net of expenses	5,005	2,180	--	836
Net cash provided by financing activities	24,369	2,280	--	836
DECREASE IN CASH AND CASH EQUIVALENTS	(5,722)	(5,027)	(5,988)	(1,346)
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(237)	64	(128)	32
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	11,851	16,814	12,008	13,165
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	5,892	11,851	5,892	11,851
Supplementary information on interest received in cash	118	30	41	5

The accompanying notes are an integral part of these condensed financial statements.

Source: RedHill Biopharma Ltd.

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