Therapix Biosciences Reports First Quarter 2018 Financial Results and Provides Business Update

TEL AVIV, Israel, May 31, 2018 /PRNewswire/ -- **Therapix Biosciences Ltd.** (Nasdaq: TRPX) **a specialty, clinical-stage pharmaceutical company focusing on the development of cannabinoid-based treatments, issued today its financial summary - first quarter 2018 vs. first quarter 2017 (Note: The functional currency of the Company is New Israeli Shekel; for presentation purposes, the financial data herein is presented in USD):**

- Net loss of $2.05 million, or $0.59 per ADS, for the three months ended March 31, 2018, compared to a net loss of $0.64 million, or $0.54 per ADS, for the three months ended March 31, 2017. The first quarter 2018 net loss included $90,000 of income due to exchange rate differences on balances of cash and cash equivalents (classified as finance income), versus $7,000 of income incurred during the corresponding period in 2017.
- Research and development ("R&D") expenses amounted to $0.99 million for the three months ended March 31, 2018, compared to approximately $0.24 million for the three months ended March 31, 2017. The increase in R&D expenses for the first quarter 2018 resulted primarily from higher expenses in connection with the clinical trials, including expenses for R&D and preclinical studies, wages and related expenses, and regulatory and other expenses.
- General and administrative expenses ("G&A") amounted to $1.13 million for the three months ended March 31, 2018, compared to $0.4 million for the three months ended March 31, 2017. The increase resulted primarily from a hiring of new employees, rise in wages and related expenses, investor relations and business expenses, business development expenses as well as professional and directors' fees. These increases were the result of the continuance of the clinical trials and an increase in the number of the Company's employees.
- Cash totaled $7.5 million as of March 31, 2018, compared to $9.2 million as of December 31, 2017. The decrease in cash primarily resulted from increased R&D and G&A expenses as detailed above. The Company currently believes that its cash balance will be sufficient to maintain its current operations into the second quarter of 2019.

Business update and developments in the Company's clinical R&D programs:

Tourette Syndrome (TS):

- The Phase IIa clinical study for THX-110 in TS at Yale University was completed. Sixteen patients were enrolled in the study. The Company recently reported top line results, and the results will be further presented at the annual meeting of the European Society for the Study of Tourette Syndrome by principal-investigator Dr. Michael Bloch.
- The Phase IIb, placebo-controlled 12-week clinical trial for THX-110 in TS is anticipated to be conducted in Germany. The Company currently anticipates first patient enrollment by the end of the third quarter, as anticipated by the original work plan and timeline. Top line results are expected in the first half of 2019.

Obstructive Sleep Apnea (OSA):

- Within the framework of Therapix's "Entourage Effect" program, the Company has initiated a Phase IIa, sponsor-initiated trial for the treatment of OSA using the Company's proprietary cannabinoid-based technology, THX-110, at Assuta Medical Center in Israel. The study was initiated earlier this month in accordance with the original work plan and timeline. Top line results are expected in the first half of 2019.

Chronic Pain:

- Within the framework of Therapix's "Entourage Effect" program, the Company has initiated a Phase IIa, investigator-initiated trial for the treatment of low back pain using THX-110, at the Clinical Research Institute, TN, USA. The study was initiated earlier this month, in accordance with the original work plan and timeline.

Mild Cognitive Impairment (MCI):

- A pre-clinical study evaluating the effect of the THX-130, proprietary ultra-low-dose THC, in a rodent model for cognitive impairment related to traumatic brain injury (TBI) was initiated in Dalhousie University, Halifax. Canada. Results are expected by the second half of this year.
- Therapix entered into a product development agreement with Cure Pharmaceuticals ("Cure") (NASDAQ: CURR), to formulate a proprietary cannabinoid-based product to deliver the ultra low dose technology. The product will be based on Cure's patented, multilayer oral thin film (OTF), CureFilm™, for the treatment of a wide range of sleep disorders.

Antimicrobial:

- We have successfully completed the first stage of our pre-clinical program to evaluate the potential efficacy of our proprietary compound THX-150.

THX-150 is a pharmaceutical composition of dronabinol (synthetic Δ9-tetrahydracannabinol) and/or palmitoylethanolamide (PEA) along with a selected antibacterial agent that possesses synergy potential. Our objective is to use our entourage technology in association with THC to increase the efficacy of existing antibiotic drugs especially in antibiotic-resistant bacteria strains. We anticipate the next step of the research will be to understand the mechanism of action of THX-150. In addition, we anticipate initiating a study in an animal model of a microbial infection to test the potential efficacy and safety of THX-150 during the second half of 2018.

Pain:

- We have successfully completed two pre-clinical studies in acute and chronic pain in rodent models evaluating the potential efficacy of the Company's proprietary compound THX-160. THX-160 is a pharmaceutical containing of synthetic CB2 receptor agonist. The efficacy of THX-160 was measured as a stand-alone therapy and as an opioid sparing agent. A second follow-up in vivo study was recently completed. The study evaluated the dosage regiment of the active ingredients, as well as their optimal therapeutic ratio.

Table 1: Consolidated Statements of Financial Position [based on an effective exchange rate of 3.514 NIS/USD as of March 31, 2018]:

	USD in Thousands	
	March 31, 2018	December 31, 2017

	Unaudited	Audited
ASSETS		
CURRENT ASSETS:		
Cash	7,509	9,195
Restricted cash	24	24
Accounts receivable	411	278
	7,944	9,497
NON-CURRENT ASSETS:		
Prepaid public offering costs	55	19
Property and equipment	56	50
	111	69
TOTAL ASSETS	**8,055**	**9,566**
LIABILITIES AND EQUITY		
CURRENT LIABILITIES:		
Trade payables	1,214	1,017
Other accounts payable	346	160
	1,560	1,177
EQUITY ATTRIBUTABLE TO EQUITY HOLDERS OF THE COMPANY:		
Share capital	3,812	3,812
Share premium	36,829	36,612
Reserve from share-based payment transactions	5,332	5,311
Foreign currency translation reserve	698	782
Transactions with noncontrolling interests	261	261
Accumulated deficit	-40,437	-38,389
Total equity	6,495	8,389
TOTAL LIABILITIES AND EQUITY	**8,055**	**9,566**

Table 2: Consolidated Statements of Profit or Loss [based on the average exchange rate of 3.46 NIS/USD for the three-month period ended March 31, 2018]:

	USD in thousands		
	Three months ended March 31,		Year ended December 31,
	2018	2017	2017
	Unaudited		Audited
Research and development expenses	$ 995	$ 240	$ 1,943
General and administrative expenses	1,139	405	3,810
	2,134	645	5,753

Other expense	-	-	1
Operating loss	2,134	645	5,754
Finance income	(88)	(9)	(1)
Finance expenses	2	-	491
Loss	**$ 2,048**	**$ 636**	**$ 6,244**
Attributable to:			
Equity holders of the Company	2,048	636	6,244
Non-controlling interests	-	-	-
	$ 2,048	**$ 636**	**$ 6,244**
Basic and diluted net loss per share attributable to equity holders of the Company	**$ 0.01**	**$ 0.01**	**$ 0.05**
Basic and diluted loss per ADS attributable to equity holders of the Company	**$ 0.59**	**$ 0.54**	**$ 2.14**

Table 3: Consolidated Statements of Comprehensive Income [based on the average exchange rate of 3.46 NIS/USD for the three-month period ended March 31, 2018]:

	USD in Thousands		
	Three months ended March 31,		**Year ended December 31,**
	2018	**2017**	**2017**
	Unaudited		**Audited**
Net loss	$ 2,048	$ 636	$ 6,244
Amounts that will not be reclassified subsequently to profit or loss:			
Adjustments arising from translating financial statements from functional currency to presentation currency	84	(315)	(461)
Total other comprehensive income (loss)	84	(315)	(461)
Total comprehensive loss	2,132	321	5,783
Attributable to:			
Equity holders of the Company	2,132	321	5,783
Non-controlling interests	-	-	-
TOTAL	**$ 2,132**	**$ 321**	**$ 5,783**

Table 4: Consolidated Statements of Changes in Equity [mainly based on the average exchange rate of 3.46 NIS/USD for the three-month period ended March 31, 2018]:

	Attributable to equity holders of the Company						
	Share capital	Share premium	Reserve from Share-based payment transactions	Transactions with non-controlling interests	Accumulated deficit	Foreign currency translation reserve	Total
	Unaudited						
	USD in thousands						
Balance at January 1, 2018	**$ 3,812**	**$ 36,612**	**$ 5,311**	**$ 261**	**$ (38,389)**	**$ 782**	**$ 8,389**
Loss	-	-	-	-	(2,048)	-	(2,048)
Total other comprehensive loss	-	-	-	-	-	(84)	(84)
Total comprehensive loss	-	-	-	-	(2,048)	(84)	(2,132)
Share-based payment	-	-	238	-	-	-	238
Expiration of share based options	-	217	(217)	-	-	-	-
Balance at March 31, 2018	**$ 3,812**	**$ 36,829**	**$ 5,332**	**$ 261**	**$ (40,437)**	**$ 698**	**$ 6,495**

	Attributable to equity holders of the Company						
	Share capital	Share premium	Reserve from Share-based payment transactions	Transactions with non-controlling interests	Accumulated deficit	Foreign currency translation reserve	Total
	Unaudited						
	USD in thousands						
Balance at January 1, 2017	**$ 1,087**	**$ 26,600**	**$ 4,449**	**$ 261**	**$ (32,145)**	**$ 321**	**$ 573**
Loss	-	-	-	-	(636)	-	(636)
Total other comprehensive loss	-	-	-	-	-	315	315
Total comprehensive loss	-	-	-	-	(636)	315	(321)
Issuance of shares (1)	189	769	-	-	-	-	958
Issuance of shares (2)	2,207	7,928	-	-	-	-	10,135
Share-based payment	-	-	64	-	-	-	64
Balance at March 31, 2017	**$ 3,483**	**$ 35,297**	**$ 4,513**	**$ 261**	**$ (32,781)**	**$ 636**	**$ 11,409**

	Attributable to equity holders of the Company						
			Reserve				

	Share capital	Share premium	Transactions from Share-based payment transactions	Transactions with non-controlling interests	Accumulated deficit	Foreign currency translation reserve	Total
	Audited						
	USD in thousands						
Balance at December 31, 2016	**$ 1,087**	**$ 26,600**	**$ 4,449**	**$ 261**	**$ (32,145)**	**$ 321**	**$ 573**
Loss	-	-	-	-	(6,244)	-	(6,244)
Total other comprehensive Income (loss)	-	-	-	-	-	461	461
Total comprehensive loss	-	-	-	-	(6,244)	461	(5,783)
Issuance of shares (1)	189	769	-	-	-	-	958
Issuance of shares (2)	2,207	7,928	-	-	-	-	10,135
Issuance of shares (3)	329	1,315	-	-	-	-	1,644
Share-based payments	-	-	862	-	-	-	862
Balance at December 31, 2017	**$ 3,812**	**$ 36,612**	**$ 5,311**	**$ 261**	**$ (38,389)**	**$ 782**	**$ 8,389**

(1) Net issuance expenses of $61,000
(2) Net issuance expenses of $1,865,000
(3) Net issuance expenses of $156,000

Table 5: Consolidated Statements of Cash Flows [based on the average exchange rate of 3.46 NIS/USD for the three-month period ended March 31, 2018]:

	USD in Thousands		
	Three months ended March 31,		Year ended December 31,
	Unaudited	Unaudited	Audited
	2018	2017	2017
Cash flows from operating activities:			
Net loss	$ (2,048)	$ (636)	$ (6,244)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	3	1	5
Gain from sale of equipment	-	-	1
Share-based payment expense	238	64	862
Finance (income) expenses, net	(90)	(7)	525
	151	58	1,393
Working capital adjustments:			
Increase in accounts receivable	(139)	(8)	(143)
Increase in trade payables	214	305	349

Increase in other accounts payable	192	87	66
	267	384	272
Net cash used in operating activities	(1,630)-	(194)	(4,579)
Cash flows from investing activities:			
Increase in restricted cash	-	-	(11)
Proceeds from sale of equipment	-	-	2
Purchase of equipment	(9)	-	(44)
Net cash used in investing activities	(9)	-	(53)
Cash flows from financing activities:			
Prepaid public offering costs	(37)	-	(18)
Proceeds from issuance of share capital (net of issuance expenses)	-	11,224	13,193
Net cash provided by financing activities	(37)	11,224	13,175
Exchange rate differences on cash and cash equivalents in foreign currency	90	7	(527)
Translation differences on cash and cash equivalents	(100)	341	503
Increase (decrease) in cash	(1,686)	11,378	8,519
Cash at the beginning of the period	9,195	676	676
Cash at the end of the period	**$ 7,509**	**$ 12,054**	**$ 9,195**

Table 6: R&D and G&A Detail [based on the average exchange rate of 3.46 NIS/USD for the three-month period ended March 31, 2018]:

	USD in Thousands		
	Three months ended March 31,		**Year ended December 31,**
	Unaudited	**Unaudited**	**Audited**
	2018	**2017**	**2017**
Research and Development Expenses:			
Clinical studies	$ 254	$ 93	$ 511
R&D and preclinical studies	155	39	362
Wages and related expenses	208	83	321
Share-based payment	47	13	103
Regulatory and other expenses	280	12	276
Chemistry & formulation studies	51	-	330
R&D expenses	***995***	***240***	***1,943***
General and Administative Expenses:			
Investor relations and buisness expenses	$ 109	$ 48	$ 871
Professional & directors fees	454	92	1,007

Regulatory expenses	15	24	80
Business development	91	-	74
Wages and related expenses	227	158	808
Office maintenance, rent and other expenses	52	32	211
Share-based payment	191	51	759
G&A expenses	***1,139***	***405***	***3,810***
TOTAL	**$ 2,134**	**$ 645**	**$ 5,753**

About Therapix Biosciences Ltd.:

Therapix Biosciences Ltd. is a specialty clinical-stage pharmaceutical company led by an experienced team of Senior Executives and Scientists. Our focus is creating and enhancing a portfolio of technologies and assets based on cannabinoid pharmaceuticals. With this focus, the Company is currently engaged in the following drug development programs based on repurposing an FDA-approved cannabinoid (Dronabinol): THX-110 for the treatment of Tourette syndrome (TS), for the treatment of Obstructive Sleep Apnea (OSA), and the treatment of pain; THX-130 for the treatment of Mild Cognitive Impairment (MCI) and Traumatic Brain Injury (TBI); THX-150 for the treatment of infectious diseases; and THX-160 for the treatment of pain. Please visit our website for more information at www.therapixbio.com

About TXH-110 (Previously referred to as THX-TS01 and THX-OSA01):

THX-110 is a combination drug candidate for the treatment of Tourette syndrome, Obstructive Sleep Apnea and pain. It is composed of two components: (1) dronabinol (an FDA approved analog of Δ9-tetrahydracannabinol, or "THC"), and (2) palmitoylethanolamide ("PEA"), which is an endogenous fatty acid amide that belongs to the class of nuclear factor agonists, which are proteins that regulate the expression of genes. The combination of THC and PEA may induce a reaction known as the "Entourage Effect". The basic tenet of the entourage effect is that cannabinoids work together, or possess synergy, and affect the body in a mechanism similar to the body's own endocannabinoid system, which is a group of molecules and receptors in the brain that mediates the psychoactive effects of cannabis. This entourage effect may account for the pharmacological actions of PEA. Based on an activity enhancement of other physiological compounds, PEA may indirectly stimulate the cannabinoid receptors by potentiating their affinity for a receptor or by inhibiting their metabolic degradation, and by doing so, may increase the uptake of cannabinoid compounds, such as THC. Thus, it is speculated that the presence of the PEA molecule could increase the efficacy of THC, while reducing the required dosage and decreasing associated deleterious adverse events.

About THX-130

THX-130 is a proprietary, innovative, ultra-low dose formulation of dronabinol, which is intended to provide a treatment for Mild Cognitive Impairment (MCI). Recent pre-clinical animal studies have found that an ultra-low dose of THC could potentially protect the brain from long-term cognitive impairment, which may be caused by aging, lack of oxygen supply, seizures or use of drugs. Certain pre-clinical studies also suggest that ultra-low doses of THC cause animals to improve performance in behavioral tests that measure learning and memory.

About THX-150:

THX-150 is a drug candidate intended for the treatment of infectious diseases. It consists of dronabinol or dronabinol with palmitoylethanolamide (PEA) and a selected antibacterial agent, which possesses antimicrobial synergy potential.

About THX-160:

THX-160 is a drug candidate intended for the treatment of pain. It consists of a CB2 receptor agonist with or without the opioid.

Forward-Looking Statements:

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 and other Federal securities laws. Because such statements deal with future events and are based on Therapix's current expectations, they are subject to various risks and uncertainties and actual results, performance or achievements of Therapix could differ materially from those described in or implied by the statements in this press release. For example, forward-looking statements include statements regarding the Company's plans with respect to its clinical trials and its intent to report material developments and information regarding such trials. In addition, historic results of scientific research and clinical and preclinical trials do not guarantee that the conclusions of future research or trials will suggest identical or even similar conclusions. The forward-looking statements contained or implied in this press release are subject to other risks and uncertainties, including those discussed under the heading "Risk Factors" in Therapix Biosciences Ltd.'s Annual Report on Form 20-F filed with the Securities and Exchange Commission (SEC) on April 30, 2018 and in subsequent filings with the SEC. Except as otherwise required by law, Therapix disclaims any intention or obligation to update or revise any forward-looking statements, which speak only as of the date they were made, whether as a result of new information, future events or circumstances or otherwise.

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Additional assets available online:

http://therapix.investorroom.com/2018-05-31-Therapix-Biosciences-Reports-First-Quarter-2018-Financial-Results-and-Provides-Business-Update