

Kitov Pharma Provides Corporate Update and Reports Full-Year 2019 Financial Results

TEL AVIV, Israel, Feb. 11, 2020 (GLOBE NEWSWIRE) -- Kitov Pharma Ltd. ("Kitov") (NASDAQ/TASE: KTOV), a clinical-stage company advancing first-in-class therapies to overcome tumor immune evasion and drug resistance, today provided a corporate update and announced financial results for the six-months and full year ended December 31, 2019.

"The recently completed year represented a transformational period for Kitov that was marked by significant progress in multiple key areas of our business," said Isaac Israel, CEO of Kitov. "Our acquisition of FameWave added an additional exciting oncology product candidate to our pipeline. With CM-24 and NT-219, we now have two promising oncology-focused drug candidates which we intend to enter the clinic this year. We have assembled a seasoned oncology clinical development team with senior and experienced executives, and we are well positioned to execute on our plans. We expect the imminent launch of Consensi in the U.S. with strong distribution partners in place to begin commercialization in 2020. Finally, our balance sheet was strengthened early in 2020 when OrbiMed, Pontifax and Arkin Holdings invested \$3.5 million of cash in Kitov, equates to a proforma cash position of approximately \$9.5 million. An additional stream of revenues expected to be generated from royalties related to sales of Consensi will further support our core oncology development programs."

Highlights & Achievements in 2019 and to Date:

New appointments to management team and Board of Directors:

- Dr. Eric Rowinsky, M.D., appointed as Chairman of Kitov's Board. In his distinguished career in academia and in the biopharma industry, Dr. Rowinsky has held various executive leadership and board roles at leading public companies, including ImClone Systems Inc., and Biogen Inc.
- Dr. Bertrand Liang, M.D., Ph.D., appointed as Chief Medical Officer. He will lead the medical affairs related to Kitov's oncology pipeline. Dr. Liang is a medical oncologist and neurologist by training and previously founded several leading biotechnology companies, and served in various senior roles in the pharma industry.
- Dr. Michael Schickler, Ph.D. appointed as the Head of Clinical Operations. Dr. Schickler joins Kitov from FameWave where he led the development of CM-24 during the transition from its former owners. He will now lead the clinical development of Kitov's full pipeline.

CM-24

CM-24 is a clinical-stage monoclonal antibody blocking CEACAM1, a well-validated target which is highly expressed in many solid tumors as well as on immune cells and plays a pivotal role in the immune system. In a monotherapy phase 1 study, CM-24 demonstrated safety and efficacy with standard dose in about 30% of patients.

Key CM-24 achievements include:

- In February 2020, we received a Notification of Issuance from the U.S. Patent and Trademark Office (USPTO) for a patent application entitled, "Humanized antibodies against CEACAM1." The patent, which expires in 2035, covers protein and DNA sequences pertaining to humanized antibodies capable of specific binding to human CEACAM1 molecules, including Kitov's first-in-class monoclonal antibody, CM-24, pharmaceutical compositions comprising these antibodies, as well as methods for their use in treating and diagnosing cancer and other conditions.
- In April 2019, the Company signed on a clinical collaboration agreement between FameWave and Bristol Myers Squibb Company for a planned Phase 1/2 clinical trials to evaluate the combination of CM-24 with nivolumab (Opdivo®), a PD-1 inhibitor, in patients with non-small cell lung cancer (NSCLC).
- In March 2019, Kitov contracted for the acquisition of FameWave, strengthening Kitov's oncology pipeline with the addition of CM-24, a novel checkpoint inhibitor. The full acquisition closed in January 2020, concurrent with OrbiMed, Pontifax and Arkin Holdings investing \$3.5 million of cash in Kitov.

NT-219

NT-219 is a first-in-class small molecule targeting both Insulin Receptor Substrates (IRS) 1/2 and Signal Transducer and Activator of Transcription 3 (STAT3), two signal proteins that are part of an anti-cancer drug resistance mechanism.

Key NT-219 achievements include:

- In January 2020, we received a notice from the European Patent Office (EPO) of Intention to Grant for its patent application entitled "Combinations of IRS/STAT3 Dual Modulators and Anti-Cancer Agents for Treating Cancer." The patent, which expires in 2036, covers the treatment of NT-219 in combination with EGFR antibodies and inhibitors.
- In September 2019, we presented newly released proof-of-concept data showing evidence of NT-219's mechanism of action in reversing cancer drug resistance in PDX models, demonstrating that NT-219 reverses tumor drug resistance to trametinib and folirinox when combined with these treatments. The data were presented in a poster at the American Association for Cancer Research's (AACR) Pancreatic Cancer: Advances in Science and Clinical Care conference in Boston.
- In June 2019, we successfully completed the laboratory phase of the IND-enabling studies for NT-219. The preclinical GLP toxicology studies have demonstrated good tolerability at the highest dose levels expected to be evaluated in Kitov's planned Phase 1/2 study.

Consensi™

Consensi™, a fixed-dose combination of celecoxib and amlodipine besylate was approved by the U.S. Food and Drug Administration (FDA) for marketing in the U.S and is expected to be launched in the U.S. during 2020 by Kitov's partner Coeptis Pharmaceuticals. Kitov has also partnered to commercialize Consensi in China and South Korea.

Key Consensi™ achievements include:

- In January 2020, Kitov received a \$1.5 million milestone reimbursement from Coeptis related to the CMC plan for Consensi™. We expect an imminent U.S. commercial launch of Consensi™ by our marketing and distribution partner, Coeptis.
- In October 2019, our marketing and distribution agreement with Coeptis Pharmaceuticals for commercialization of Consensi™ in the U.S has been amended. Under the new terms of the agreement, Kitov will receive up to \$99.5M in milestone and reimbursement payments plus 20% in royalties, with a minimum aggregate of \$7 million over the next three years.
- In May 2019, we received a notice of allowance from the USPTO for its Patent Application 16/008,538, "Celecoxib and Amlodipine formulation and methods of making the same," covering the proprietary formulation of Consensi™, Kitov's commercial-stage product.

Full US Prescribing Information, including BOXED WARNING and Medication Guide is available at: www.consensi.com.

Financial Results for the Year Ended December 31, 2019

Revenues

Total revenues for the year ended December 31, 2019, were \$1.0 million, compared to \$1.0 million in the year ended December 31, 2018. The revenues for the year ended December 31, 2019, consisted of the first milestone payment related to Consensi™ development from Coeptis Pharmaceuticals.

Research and Development Expenses

Research and development (R&D) expenses for the year ended December 31, 2019, were \$2.7 million, a decrease of \$2.6 million, or 49.3%, compared to \$5.3 million for the year ended December 31, 2018. The decrease in research and development expenses resulted primarily from a decrease in costs related to the clinical development of Consensi™ following FDA approval of the drug.

Selling, General and Administrative Expenses

Selling, General and administrative (SG&A) expenses for the year ended December 31, 2019, were \$6.1 million, an increase of \$0.9 million, or 18.6%, compared to \$5.2 million for the year ended December 31, 2018. The increase in selling, general and administrative expenses resulted primarily from a \$0.9 million annual fee paid to the FDA related to Consensi™ which will be assumed by our marketing partner in the US starting from 2020.

Operating Loss

Operating loss for the year ended December 31, 2019, were \$7.2 million, a decrease of \$0.6 million, or 8.5%, compared to \$7.8 million for the year ended December 31, 2018.

On a non-IFRS basis (as described and reconciled below), adjusted operating loss for the year ended December 31, 2019, was \$5.9 million, a decrease of \$1.2 million from \$7.1 million for the year ended December 31, 2018. The decrease was due to the decrease in R&D expenses mentioned above and a decrease in various SG&A expenses offset by a one-time increase in FDA fee and a one-time decrease in other income.

Net Loss

Net loss for the year ended December 31, 2019, was \$5.9 million, or (\$0.30) per diluted share, compared to \$5.6 million, or (\$0.39) per diluted share, for the year ended December 31, 2018.

Financial Results for the 6 months Ended December 31, 2019

Research and Development Expenses

R&D expenses for the six-month period ended December 31, 2019, were \$1 million, a decrease of \$1.4 million, or 58.3%, compared to \$2.4 million for the six-month period ended December 31, 2018. The decrease in research and development expenses resulted primarily from a decrease in costs related to the development of Consensi™ and decrease in preclinical development costs for NT219.

Selling, General and Administrative Expenses

SG&A expenses for the six-month period ended December 31, 2019, were \$2.8 million, an increase of \$1 million, or 55.5%, compared to \$1.8 million for the six-month period ended December 31, 2018. The increase in SG&A expenses resulted primarily from the one-time fee paid to the FDA relating to Consensi™ as mentioned above and increase in employees stock option costs.

Operating Loss

Operating loss for the six-month period ended December 31, 2019, was \$3.6 million, an increase of \$0.2 million, or 5.9%, compared to \$3.4 million for the six-month period ended December 31, 2018.

On a non-IFRS basis (as described and reconciled below), adjusted operating loss for the six-month period ended December 31, 2019, was \$2.8 million, a decrease of \$0.5 million from \$3.3 million for the six-month period ended December 31, 2018. The decrease was due to the decrease in R&D expenses mentioned above and a decrease in various SG&A expenses offset by a one-time increase in FDA fee.

Net Loss

Net loss for the six-month period ended December 31, 2019, was \$3.3 million, or \$0.17 per diluted share, compared to \$0.4 million, or \$0.02 per diluted share, for the six-month period ended December 31, 2018. The increase in net loss was mainly due to decrease of \$2.6M in income from a change in the fair value of derivatives.

Cash & Cash Equivalents

At December 31, 2019, the Company had \$4.4 million in cash and cash equivalents compared to \$5.2 million at the end of December 2018. In January 2020, Kitov received a \$1.5 million milestone payment from Coepris. This payment, in addition to the \$3.5 million financing from Pontifax, Orbimed and Arkin, equates to a proforma cash position of approximately \$9.5 million at December 31, 2019.

Adjusted operating loss

Adjusted operating loss is defined as operating loss, plus non-cash share-based compensation expenses. Our management believes that excluding non-cash charges related to share-based compensation provides useful information to investors because of its non-cash nature, varying available valuation methodologies among companies and the subjectivity of the assumptions and the variety of award types that a company can use under the relevant accounting guidance, which may obscure trends in our core operating performance. We present adjusted operating loss because we use this non-IFRS financial measures to assess our operational performance, for financial and operational decision-making, and as a means to evaluate period-to-period comparisons on a consistent basis. Management believes this non-IFRS financial measure is useful to investors because: (1) it allows for greater transparency with respect to key metrics used by management in its financial and operational decision-making; and (2) it exclude the impact of non-cash item that is not directly attributable to our core operating performance and that may obscure trends in the core operating performance of the business. Non-IFRS financial measures have limitations as an analytical tool and should not be considered in isolation from, or as a substitute for, our IFRS results. We expect to continue reporting non-IFRS financial measures, adjusting for the item described above, and we expect to continue to incur expenses similar to certain of the non-cash, non-IFRS adjustments described above. Accordingly, unless otherwise stated, the exclusion of this and other similar items in the presentation of non-IFRS financial measures should not be construed as an inference that these items are unusual, infrequent or non-recurring. Adjusted operating loss is not a recognized term under IFRS and do not purport to be an alternative to IFRS net operating loss as an indicator of operating performance or any other IFRS measure. Moreover, because not all companies use identical measures and calculations, the presentation of adjusted operating loss may not be comparable to other similarly titled measures of other companies.

About Kitov Pharma

Kitov Pharma (Kitov Pharma Ltd.; NASDAQ/TASE: KTOV) is a clinical-stage company focusing on advancing first-in-class therapies to overcome tumor immune evasion and drug resistance, to create successful long-lasting treatments for people with cancer. Kitov's oncology pipeline includes NT-219 and CM-24. NT-219 is a small molecule targeting the novel cancer drug resistance pathways IRS1/2 and STAT3. Kitov is currently advancing NT-219 in combination with cetuximab as a third-line or second-line treatment option for the treatment of recurrent and metastatic squamous cell carcinoma of head & neck cancer (SCCHN). CM-24 is a monoclonal antibody blocking CEACAM1, a novel immune checkpoint that supports tumor immune evasion and survival through multiple pathways. Kitov will advance CM-24 as a combination therapy with anti-PD1 checkpoint inhibitors for the treatment of non-small cell lung cancer (NSCLC). Kitov has entered into a clinical collaboration agreement with Bristol Myers Squibb Company (NYSE:BMJ) for the planned Phase 1/2 clinical trials to evaluate the combination of CM-24 with the PD-1 inhibitor nivolumab (Opdivo®). Kitov is also the owner of Consensi™, a fixed-dose combination of celecoxib and amlodipine besylate, for the simultaneous treatment of osteoarthritis pain and hypertension which was approved by the FDA for marketing in the U.S and is expected to be launched in the U.S. during 2020 by its partner Coepris Pharmaceuticals. Kitov has also partnered to commercialize Consensi in China and South Korea. The company is headquartered in Tel Aviv, Israel. For more information, please visit <http://www.kitovpharma.com>.

Forward-Looking Statements and Kitov's Safe Harbor Statement

Certain statements in this press release that are forward-looking and not statements of historical fact are forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include, but are not limited to, statements that are not statements of historical fact, and may be identified by words such as "believe", "expect", "intend", "plan", "may", "should", "could", "might", "seek", "target", "will", "project", "forecast", "continue" or "anticipate" or their negatives or variations of these words or other comparable words or by the fact that these statements do not relate strictly to historical matters. You should not place undue reliance on these forward-looking statements, which are not guarantees of future performance. Forward-looking statements reflect our current views, expectations, beliefs or intentions with respect to future events, and are subject to a number of assumptions, involve known and unknown risks, many of which are beyond our control, as well as uncertainties and other factors that may cause our actual results, performance or achievements to be significantly different from any future results, performance or achievements expressed or implied by the forward-looking statements. Important factors that could cause or contribute to such differences include, among others, risks relating to: different results from the expected benefits, synergies and costs of the acquisition of FameWave by Kitov; management plans relating to the transaction; the plans, strategies and objectives of management for future operations; product development for NT219 and CM-24; the potential future financial impact of the transaction; and any assumptions underlying any of the foregoing; the process by which early stage therapeutic candidates such as NT219 and CM-24 could potentially lead to an approved drug product is long and subject to highly significant risks, particularly with respect to a joint development collaboration; the fact that drug development and commercialization involves a lengthy and expensive process with uncertain outcomes; our ability to successfully develop and commercialize our pharmaceutical products; the expense, length, progress and results of any clinical trials; the lack of sufficient funding to finance the clinical trials; the impact of any changes in regulation and legislation that could affect the pharmaceutical industry; the difficulty in receiving the regulatory approvals necessary in order to commercialize our products; the difficulty of predicting actions of the U.S. Food and Drug Administration or any other applicable regulator of pharmaceutical products; the regulatory environment and changes in the health policies and regimes in the countries in which we operate; the uncertainty surrounding the actual market reception to our pharmaceutical products once cleared for marketing in a particular market; the introduction of competing products; patents attained by competitors; dependence on the effectiveness of our patents and other protections for innovative products; our ability to obtain, maintain and defend issued patents with protective claims; the commencement of any patent interference or infringement action; our ability to prevail, obtain a favorable decision or recover damages in any such action; and the exposure to litigation, including patent litigation, and/or regulatory actions, and other factors that are discussed in our in our Annual Report on Form 20-F for the year ended December 31, 2018 and in our other filings with the SEC, including our cautionary discussion of risks and uncertainties under 'Risk Factors' in our Registration Statements and Annual Reports. These are factors that we believe could cause our actual results to differ materially from expected results. Other factors besides those we have listed could also adversely affect us. Any forward-looking statement in this press release speaks only

as of the date which it is made. We disclaim any intention or obligation to publicly update or revise any forward-looking statement, or other information contained herein, whether as a result of new information, future events or otherwise, except as required by applicable law. You are advised, however, to consult any additional disclosures we make in our reports to the SEC, which are available on the SEC's website, <http://www.sec.gov>

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Kitov Pharma

Consolidated Unaudited Statements of Financial Position

	As of December 31,	
	2019	2018
	USD thousands	USD thousands
Assets		
Cash and cash equivalents	4,385	5,163
Short term deposits	10	1,521
Financial assets	2,000	-
Other current assets	1,907	1,830
Total current assets	8,302	8,514
Right to use assets	206	-
Fixed assets, net	38	37
Intangible assets	6,172	6,172
Total assets	14,718	14,723
Liabilities		
Lease liability – short term	195	-
Accounts payable	1,243	705
Other payables	2,106	2,055
Derivative liabilities	-	554
Total current liabilities	3,544	3,314
Non-current liabilities		
Lease liability	28	-
Post-employment benefit liabilities	285	405
Total non – current liabilities	313	405
Equity		
Share capital, no par value	-	-
Share premium	46,986	44,597
Receipts on account of warrants	9,874	7,982
Capital reserve for share-based payments	3,182	1,714
Capital reserve from transactions with related parties	761	761
Capital reserve from transactions with non- controlling interest	(859)	(859)
Accumulated loss	(49,521)	(43,672)
Equity attributable to owners of the Company	10,423	10,523

Non-controlling interests	438	481
Total equity	10,861	11,004
Total liabilities and equity	14,718	14,723

Kitov Pharma

Consolidated Unaudited Statements of Operations

	For the year ended December 31,		For the six months ended December 31,	
	2019 USD thousands	2018 USD thousands	2019 USD thousands	2018 USD thousands
Revenues	1,000	1,000	-	-
Research and development expenses	2,674	5,268	986	2,426
Sales, general and administrative expenses	6,078	5,195	2,773	1,801
Reimbursement of legal fees	(596)	(743)	(166)	(743)
Other income	-	(894)	-	(28)
Total operating expenses	8,156	8,826	3,593	3,456
Operating loss	7,156	7,826	3,593	3,456
Net change in fair value of derivatives	(1,509)	(2,740)	(517)	(3,197)
Finance expenses	181	576	73	196
Finance income	(151)	(93)	(78)	(69)
Finance income, net	(1,479)	(2,257)	(522)	(3,070)
Other expenses	216	-	216	-
Loss for the year	5,893	5,569	3,287	386
Loss attributable to:				
Owners of the Company	5,850	5,200	3,275	349
Non-controlling interests	43	369	12	37
	5,893	5,569	3,287	386
Loss per share data				
Basic and diluted loss per share – USD	0.30	0.39	0.17	0.02
Number of shares used in calculating basic and diluted loss per share	19,367,784	14,205,301	19,548,662	15,975,408

Kitov Pharma

Consolidated Unaudited Statements of Cash Flow

	For the year ended December 31,		For the six months ended December 31,	
	2019 USD thousands	2018 USD thousands	2019 USD thousands	2018 USD thousands
Cash flows from operating activities:				
Loss for the year	(5,893)	(5,569)	(3,287)	(386)
Adjustments:				
Depreciation	179	7	84	4

Finance expense, net	(1,479)	(2,257)	(522)	(3,070)
Share-based payments	1,272	773	773	161
Income in regards with settlement with a minority shareholder of a subsidiary	-	(894)	-	(28)
	(5,921)	(7,940)	(2,952)	(3,319)
Changes in assets and liabilities:				
Changes in other current assets	62	(1,111)	(891)	(1,313)
Changes in accounts payable	503	393	361	(132)
Changes in other payables	(77)	241	149	(171)
Changes in post-employment benefit liabilities	(148)	(63)	22	(63)
	340	(540)	(359)	(1,679)
Net cash used in operating activities	(5,581)	(8,480)	(3,311)	(4,998)
Cash flows from investing activities:				
Investment in financial asset and loan granted	(2,100)	-	(100)	-
Decrease in short term deposits	1,511	1,967	5,011	5,028
Interest received	151	93	121	69
Acquisition of fixed assets	(11)	(16)	(3)	(11)
Net cash provided by (used in) investing activities	(449)	2,044	5,029	5,086
Cash flows from financing activities:				
Proceeds from issuance of shares and ADSs	2,594	4,683	-	-
Share and ADS issuance expenses paid	(264)	(407)	-	-
Proceeds from issuance of warrants	3,406	3,467	-	-
Warrants issuance expenses paid	(347)	(301)	-	-
Receipts from warrant exercise	43	515	-	-
Repayment of lease liability	(171)	-	(82)	-
Interest paid	(28)	(169)	(14)	(162)
Net cash provided by financing activities:	5,233	7,788	(96)	(162)
Net increase (decrease) in cash and cash equivalents	(797)	1,352	1,622	(74)
Cash and cash equivalents at the beginning of the period	5,163	3,947	2,757	5,363
Effect of translation adjustments on cash and cash equivalents	19	(136)	6	(126)
Cash and cash equivalents at end of the period	4,385	5,163	4,385	5,163

Kitov Pharma Reconciliation of Non-IFRS Financial Results

Reconciliation of Adjusted Operating Loss

	For the year ended December 31,		For the six months ended December 31,	
	2019	2018	2019	2018
	USD	USD	USD	USD
	thousands	thousands	thousands	thousands
Operating loss for the year	7,156	7,826	3,593	3,456
Less ESOP expenses	(1,272)	(719)	(773)	(161)
	5,884	7,107	2,820	3,295