
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

**Report of Foreign Private Issuer
Pursuant to Rule 13a-16 or 15d-16
of the Securities Exchange Act of 1934**

For the month of February 2019

Commission File Number: 001-37643

KITOV PHARMA LTD.
(Translation of registrant's name into English)

**One Azrieli Center, Round Tower,
Tel Aviv 6701101, Israel**
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F ☒

Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): _____

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): _____

Kitov Pharma Ltd. (the “Company” or the “Registrant”) is announcing that on February 7, 2019, the Company issued a press release, “**Kitov Pharma Reports Year End 2018 Financial Results and Provides Business Update**”, which is attached hereto as Exhibit 99.1.

Exhibit 99.1 [Press Release](#)

This Form 6-K, including Exhibit 99.1, is hereby incorporated by reference into each of the Registrant’s Registration Statements on Form F-3 filed with the Securities and Exchange Commission on December 12, 2016 (Registration file numbers 333-207117, 333-211477 and 333-215037), the Registrant’s Registration Statement on Form S-8 filed with the Securities and Exchange Commission on May 20, 2016 (Registration file number 333-211478), the Registrant’s Registration Statement on Form S-8 filed with the Securities and Exchange Commission on June 6, 2017 (Registration file number 333-218538), and the Registrant’s Registration Statement on Form F-3, as amended, originally filed with the Securities and Exchange Commission on July 16, 2018 (Registration file number 333-226195).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

KITOV PHARMA LTD.

February 7, 2019

By: /s/ Isaac Israel
Isaac Israel
CEO and Director

Kitov Pharma Reports Year End 2018 Financial Results and Provides Business Update

TEL AVIV, Israel, February 7, 2019 -- Kitov Pharma (NASDAQ/TASE: KTOV), an innovative pharmaceutical company, today reported its unaudited financial results for the year ended December 31, 2018 and provided a business update.

Highlights & Achievements in 2018 and to Date:

- Approximately \$13 million cash on hand at the beginning of 2019 based on a reported cash balance of \$6.7 million on December 31, 2018, plus net \$5.5 million raise through financing in January, and a \$1 million milestone payment from Kitov's U.S. distributor for Consensi™.
- \$4.2 million decrease in loss from operations to \$7.8 million in 2018 from \$12.0 million in 2017 and a \$7.3 million decrease in net loss to \$5.6 million in 2018 from \$12.9 million in 2017.
- 72% decrease in loss per diluted share to \$0.39 in 2018 from \$1.38 in 2017.
- R&D expenses in 2018 were approximately \$5.3 million compared to \$4.6 million in 2017.
- Consensi™ was approved by the U.S. FDA in June 2018 and is licensed for commercialization in the U.S., China, and South Korea;

"We are very proud of the major achievement of gaining FDA approval for our lead drug candidate, Consensi™, as well as the excellent progress we have made in our NT-219 pre-clinical development program during 2018," stated Isaac Israel, Chief Executive Officer of Kitov Pharma. "We are working productively with Coeptis Pharmaceuticals and its outstanding team to launch Consensi™ in the U.S. market to create better patient compliance and improved treatment for people living with osteoarthritis pain and hypertension. Additionally, we are very satisfied with the on-target execution of our NT-219 oncology program and we look forward to initiating clinical trials later this year. We are committed to continuing to unlock substantial value in our business by leveraging our team's deep regulatory expertise and drug development experience, complemented by targeted business development efforts, in order to maximize the potential of our therapeutic candidates. We strengthened our balance sheet recently with the additional gross financing of \$6 million in January 2019 as we progress with our goals to achieve a major clinical milestone with NT-219."

NT-219 - Small Molecule Oncology Drug

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:

- Positive results were reported in a pre-clinical study which evaluated NT-219 in combination with gemcitabine in a patient-derived xenograft (PDX) model of pancreatic cancer. The study was conducted in accordance with guidance from the U.S. FDA and the results support the planned submission of an Investigational New Drug (IND) application for NT-219. Kitov is preparing for initiation of clinical trials in 2019.
 - At the Fourth CRI-CIMT-EATI-AACR International Cancer Immunotherapy Conference in New York, Kitov presented an abstract in a poster session demonstrating NT-219's efficacy in synergy with immuno-oncology therapies, which are widely used today, but to which unfortunately, most patients still do not respond. In double autologous PDX models, dosing with NT-219 converted tumors that were resistant to pembrolizumab (Keytruda®) into responsive tumors. The models also demonstrated the efficacy of NT-219 in enhancing the immunotherapeutic potential of cetuximab (Erbix®).
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- Kitov announced new findings from the Company's ongoing collaboration with researchers from the Hebrew University of Jerusalem. The data reveal NT-219's high affinity and selective binding to its target proteins, demonstrating that NT-219 binds directly to IRS1/2 and to STAT3, both known modulators of tumor survival, metastasis and drug resistance. Data showed that a short exposure of cancerous cells to NT-219 was sufficient to trigger irreversible shutdown of these pathways, resulting in a long-term anti-cancer effect.

Consensi™

Consensi™, a combination drug that simultaneously treats pain caused by osteoarthritis and treats hypertension, is comprised of two FDA approved drugs, celecoxib (Celebrex®), a non-steroidal anti-inflammatory drug (NSAID) for the treatment of pain caused by osteoarthritis, and amlodipine besylate (Norvasc®) a drug designed to treat hypertension. Hypertension is one of the side effects of using NSAIDs including celecoxib.

Consensi™, under patent protection in the U.S. until 2030, and will be the only NSAID whose labeling indicates a reduction of blood pressure and consequent risk reduction of heart attack, stroke, and death. The therapy may contribute to improved patient compliance and improved patient health, thereby lowering overall health care costs.

Kitov currently has three signed licensing and distribution agreements for the drug in the U.S., China and South Korea. The Company believes that successful commercialization of Consensi™ in the U.S. by Coeptis Pharmaceuticals will be a transformational value-creating event for Kitov.

Key Consensi™ accomplishments include:

- The FDA approved Consensi™ for marketing in the U.S. for once daily use in three dosage forms, corresponding to the current approved dosages of amlodipine (2.5, 5, and 10 mg) for hypertension and a 200 mg dose of celecoxib for the treatment of osteoarthritis pain.
- Kitov signed a definitive License Agreement for Consensi™ with Hebei Changshan Biochemical Pharmaceutical Co., Ltd. (CSBio), a Chinese public company traded on the Shenzhen Stock Exchange. Upon receipt of marketing authorization in China, CSBio will have the exclusive right and license to import, manufacture, distribute, and sell Consensi™ in China. Under the terms of the agreement, Kitov is entitled to receive up to an aggregate of \$3.5 million for regulatory milestones, of which Kitov has already received \$1 million. In addition, Kitov is entitled to receive up to an aggregate of \$6.0 million for predefined commercial milestones and up to 12% royalties on net sales.
- Kitov signed an exclusive marketing and distribution agreement with Coeptis Pharmaceuticals for the U.S. market. The agreement provides for total milestone payments from Coeptis to Kitov of \$3.5 million, of which Kitov has already received \$1 million upon execution of the agreement, and additional milestone payments are due upon completion of an agreed manufacturing plan and upon first commercial sales in the U.S. In addition, Kitov will be paid 40%-60% of Coeptis' net profit on Consensi™ sales.

Expected Significant Upcoming Kitov Milestones for 2019:

- Complete pre-clinical development plan for NT-219; submit an IND application to the FDA; and start clinical trials in combination with approved oncology drugs to increase efficacy, expand target populations and treatment duration.
- Execute collaboration agreements with potential strategic partners for the development of NT-219.
- In-license at least one additional oncology drug candidate, either at a late pre-clinical or early/mid-stage clinical stage.
- Complete preparation for launch of Consensi™ in the U.S. with commercial partner Coeptis Pharmaceuticals.

Financial Results for the Year Ended December 31, 2018

Research and development expenses for the year ended December 31, 2018 were \$5.3 million, an increase of \$0.7 million, or 15.2%, compared to \$4.6 million for the year ended December 31, 2017. The increase resulted primarily from higher expenses in 2018 associated with NT-219 preclinical and CMC development. Kitov expects a similar level of R&D expenditure, mainly for the development of NT-219, in 2019.

General and administrative expenses, including reimbursement from insurance for legal fees, for the year ended December 31, 2018 were \$4.5 million, a decrease of \$1.9 million, or 29.7%, compared to \$6.4 million for the year ended December 31, 2017. The decrease resulted primarily from higher legal expenses in 2017 associated with class action claims and reimbursement for these legal fees in 2018.

Kitov's operating loss for the year ended December 31, 2018 amounted to \$7.8 million, compared with an operating loss of \$12 million for the year ended December 31, 2017, a 35% decrease. The decrease in operating loss reflects \$1 million in revenue in 2018 and the significant decrease in general and administrative expenses as mentioned above during 2018 offset by an increase in research and development expenses.

Kitov's net loss for the year ended December 31, 2018 amounted to \$5.6 million, compared with a net loss of \$12.9 million for the year ended December 31, 2017 as a result of the decrease in operating loss mentioned above, finance income of \$2.3 million in 2018, mainly a result of decrease in fair value of derivatives compared to finance expenses of \$1 million in 2017, mainly a result of increase in fair value of derivatives.

Kitov held \$6.7 million in cash, cash equivalents and short-term bank deposits as of December 31, 2018. After the end of 2018, Kitov raised a net of \$5.5 million through an offering in January 2019.

Financial Results for the 6 Months Period Ended December 31, 2018

Research and development expenses for the six-month period ended December 31, 2018 were \$2.4 million, an increase of \$0.3 million, or 14.3%, compared to \$2.1 million for 2nd half of 2017. The increase resulted primarily from higher expenses in 2018 associated with preclinical and CMC development for NT-219.

General and administrative expenses, including reimbursement from insurance for legal fees, for the six-month period ended December 31, 2018 were \$1.1 million, a decrease of \$2.8 million, or 71.8%, compared to \$3.9 million for the six-month period ended December 31, 2017. The decrease resulted primarily from decrease in legal and consulting expenses, reimbursement from insurance and decrease in salary related expenses including ESOP costs in 2018.

Kitov's operating loss for the six-month period ended December 31, 2018 amounted to \$3.5 million, compared with an operating loss of \$6.0 million for the six-month period ended December 31, 2017. The decrease in operating loss reflects the significant decrease in general and administrative expenses as mentioned above during 2018.

Kitov's net loss for the six-month period ended December 31, 2018 amounted to \$0.4 million, compared with a net loss of \$6.9 million for the six-month period ended December 31, 2017.

Consolidated Unaudited Statements of Financial Position

	As of December 31,	
	2018	2017
	USD	USD
	thousands	thousands
Assets		
Cash and cash equivalents	5,163	3,947
Short term deposits	1,521	3,488
Other current assets	1,830	548
Total current assets	8,514	7,983
Fixed assets, net	37	28
Intangible assets	6,172	6,172
Total assets	14,723	14,183
Liabilities		
Accounts payable	705	215
Other payables	2,055	(*) 1,746
Derivative instruments	554	2,012
Total current liabilities	3,314	3,973
Non-current liabilities		
Derivative instruments	-	1,030
Post-employment benefit liabilities	405	492
Total non – current liabilities	405	1,522
Equity		
Share capital, no par value	-	-
Share premium	44,597	35,979
Receipts on account of warrants	7,982	7,415
Capital reserve for share-based payments	1,714	1,725
Capital reserve from transactions with related parties	761	761
Capital reserve from transactions with non- controlling interest	(859)	-
Accumulated loss	(43,672)	(*) (38,472)
Equity attributable to owners of the Company	10,523	7,408
Non-controlling interests	481	1,280
Total equity	11,004	8,688
Total liabilities and equity	14,723	14,183

(*) Restated due to full retrospective method of adoption of IFRS 15, *Revenue from Contracts with Customers*.

Consolidated Unaudited Statements of Operations and Other Comprehensive Income

	For the year ended December 31,		For the six months ended December 31,	
	2018	2017	2018	2017
	USD thousands	USD thousands	USD thousands	USD thousands
Revenues	1,000	(*) 100	-	(*) 100
Research and development expenses	5,268	4,640	2,426	2,124
General and administrative expenses	5,195	(*) 6,397	1,801	(*) 3,873
Reimbursement of legal fees	(743)	-	(743)	-
Other expenses (income)	(894)	1,029	(28)	-
Total operating expenses	8,826	12,066	3,456	5,997
Operating loss	7,826	11,966	3,456	5,897
Net change in fair value of derivatives	(2,740)	1,049	(3,197)	1,049
Finance expenses	576	26	196	19
Finance income	(93)	(128)	(69)	(65)
Finance expenses (income), net	(2,257)	947	(3,070)	1,003
Loss for the year	5,569	12,913	386	6,900
Other comprehensive loss Items that will not be classified to profit or loss				
Re-measurement of defined benefit liability	-	95	-	95
Total comprehensive loss for the year	5,569	13,008	386	6,995
Loss attributable to:				
Owners of the Company	5,200	12,177	349	6,353
Non-controlling interests	369	736	37	547
	5,569	12,913	386	6,900
Total comprehensive loss attributable to:				
Owners of the Company	5,200	12,272	349	6,448
Non-controlling interests	369	736	37	547
	5,569	13,008	386	6,995
Loss per share data				
Basic and diluted loss per share – USD	0.39	(**) 1.38	0.02	(**) 0.65
Number of shares used in calculating basic and diluted loss per share	14,205,301	9,456,952	15,975,408	10,704,180

(*) Restated due to full retrospective method of adoption of IFRS 15, *Revenue from Contracts with Customers*.

(**) Restated to reflect a 20:1 reverse share split, that took place in January 2019.

Consolidated Unaudited Statements of Cash Flow

	For the year ended December 31,		For the six months ended December 31,	
	2018	2017	2018	2017
	USD thousands	USD thousands	USD thousands	USD thousands
Cash flows from operating activities:				
Loss for the year	(5,569)	(*) (12,913)	(386)	(*) (6,900)
Adjustments:				
Depreciation	7	4	4	2
Finance expense (income), net	(2,257)	947	(3,070)	1,003
Share-based payments	773	2,308	161	1,025
Expenses (income) in regards with settlement with a minority shareholder of a subsidiary	(894)	1,000	(28)	-
	<u>(7,940)</u>	<u>(8,654)</u>	<u>(3,319)</u>	<u>(4,870)</u>
Changes in assets and liabilities:				
Changes in other receivables	(1,111)	(273)	(1,313)	263
Changes in accounts payable	393	(491)	(132)	(251)
Changes in other payables	241	(*) 650	(171)	(*) 1,048
Changes in post-employment benefit liabilities	(63)	141	(63)	(126)
	<u>(540)</u>	<u>27</u>	<u>(1,679)</u>	<u>934</u>
Net cash used in operating activities	<u>(8,480)</u>	<u>(8,627)</u>	<u>(4,998)</u>	<u>(3,936)</u>
Cash flows from investing activities:				
Acquisition of subsidiary	-	(1,732)	-	-
Decrease (increase) in short term deposits	1,967	4,411	5,028	4,054
Interest received	93	106	69	106
Acquisition of fixed assets	(16)	(13)	(11)	(10)
Net cash provided by (used in) investing activities	<u>2,044</u>	<u>2,772</u>	<u>5,086</u>	<u>4,150</u>
Cash flows from financing activities:				
Repayment of loans from related parties	-	(130)	-	-
Short-term credit from bank	-	(16)	-	-
Proceeds from issuance of shares and ADSs	4,683	2,419	-	2,419
Share and ADS issuance expenses paid	(407)	(245)	-	(245)
Proceeds from issuance of warrants	3,467	1,107	-	1,107
Warrants issuance expenses paid	(301)	(114)	-	(114)
Receipts from warrant exercise	515	-	-	-
Interest paid	(169)	(26)	(162)	(18)
Net cash provided by financing activities:	<u>7,788</u>	<u>2,995</u>	<u>(162)</u>	<u>3,149</u>
Net increase (decrease) in cash and cash equivalents	<u>1,352</u>	<u>(2,860)</u>	<u>(74)</u>	<u>3,363</u>
Cash and cash equivalents at the beginning of the period	<u>3,947</u>	<u>6,758</u>	<u>5,363</u>	<u>527</u>
Effect of translation adjustments on cash and cash equivalents	<u>(136)</u>	<u>49</u>	<u>(126)</u>	<u>57</u>
Cash and cash equivalents at end of the period	<u><u>5,163</u></u>	<u><u>3,947</u></u>	<u><u>5,163</u></u>	<u><u>3,947</u></u>

(*) Restated due to full retrospective method of adoption of IFRS 15, *Revenue from Contracts with Customers*,

About Consensi™

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

Indications and Usage:

Consensi™ is a combination of amlodipine besylate, a calcium channel blocker, and celecoxib, a nonsteroidal anti-inflammatory drug (NSAID), indicated for patients for whom treatment with amlodipine for hypertension and celecoxib for osteoarthritis are appropriate. Lowering blood pressure reduces the risk of fatal and nonfatal CV events, primarily strokes and myocardial infarctions.

Limitations of Use:

Consensi™ is only available in a celecoxib strength of 200 mg and is only to be taken once daily.

Important Safety Information (ISI) for Consensi™

The following ISI is based on the Highlights section of the U.S. Prescribing Information for Consensi™. Please consult the full Prescribing Information for all of the labelled safety information for Consensi™.

Nonsteroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular (CV) thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in the treatment and may increase with duration of use.

Consensi™ is contraindicated in the setting of coronary artery bypass graft (CABG) surgery.

NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events, including bleeding, ulceration and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events.

Consensi™ is contraindicated in patients with a known hypersensitivity to amlodipine, celecoxib or any of its inactive ingredients.

Consensi™ is contraindicated in patients with a known history of asthma, urticaria or other allergic-type reactions after taking aspirin or other NSAIDs and in the setting of CABG surgery.

Consensi™ is contraindicated in patients with known demonstrated allergic-type reactions to sulfonamides.

Significant warnings and precautions related to Consensi™ include the following:

Patients should be warned about the potential signs and symptoms of hepatotoxicity and hepatic failure. Physicians should discontinue Consensi™ if abnormal liver tests persist or worsen, or if clinical signs and symptoms of liver disease develop.

Patients taking some antihypertensive medications may have impaired response to these therapies when taking NSAIDs. Physicians should carefully monitor blood pressure.

Symptomatic hypotension is possible, particularly in patients with severe aortic stenosis.

Worsening angina and acute myocardial infarction, particularly in patients with severe obstructive coronary artery disease, is possible.

Physicians should avoid use of Consensi™ in patients with severe heart failure.

Physicians should monitor renal function in patients with renal or hepatic impairment, heart failure, dehydration, or hypovolemia, and avoid the use of Consensi™ in patients with advanced renal disease.

Patients should seek emergency help if an anaphylactic reaction occurs.

Consensi™ is contraindicated in patients with aspirin-sensitive asthma. Monitor patients with preexisting asthma (without aspirin sensitivity).

Physicians should discontinue Consensi™ at the first appearance of skin rash or other signs of hypersensitivity.

NSAIDs such as Consensi™ can cause premature Closure of Fetal Ductus Arteriosus.

Avoid use in pregnant women starting at 30 weeks of gestation.

Physicians should monitor hemoglobin or hematocrit in patients with any signs or symptoms of anemia.

Consensi™ is not recommended in patients with moderate or severe hepatic impairment or severe renal insufficiency.

Consensi™ is not recommended in Poor Metabolizers of CYP2C9 Substrates.

To report SUSPECTED ADVERSE REACTIONS, contact Kitov Pharma at 1-800-651-6606 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

About Kitov Pharma

Kitov Pharma (Kitov Pharma Ltd.; NASDAQ/TASE: KTOV) is an innovative pharmaceutical drug development company. Leveraging deep regulatory and clinical-trial expertise, Kitov's veteran team of healthcare and business professionals maintains a proven track record in streamlined end-to-end drug development and approval. Kitov's NT219, a novel patented small molecule designed to overcome cancer drug resistance, is currently in pre-clinical development. In addition, Kitov's flagship combination drug, Consensi™, treating osteoarthritis pain and hypertension simultaneously, was approved by the FDA for marketing in the U.S and is partnered in the U.S., China and South Korea. By lowering development risk and cost through fast-track regulatory approval of novel therapeutics, Kitov plans to deliver rapid ROI and long-term potential to investors, while making a meaningful impact on people's lives. For more information on Kitov, the content of which is not part of this press release, 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: uncertainties associated with 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; the uncertainty surrounding an investigation by the Israel Securities Authority into our historical public disclosures and the potential impact of such investigation on the trading of our securities or on our clinical, commercial and other business relationships, or on receiving the regulatory approvals necessary in order to commercialize our products, and other factors that are discussed in our in our Annual Report on Form 20-F for the year ended December 31, 2017 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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