Nektar Therapeutics Reports Financial Results for the First Quarter of 2018

May 10, 2018

SAN FRANCISCO, May 10, 2018 /PRNewswire/ -- Nektar Therapeutics (Nasdaq: NKTR) today reported its financial results for the first quarter ended March 31, 2018.

Cash and investments in marketable securities at March 31, 2018 were $333.8 million as compared to $353.2 million at December 31, 2017. This does not include the $1.0 billion upfront payment and $850.0 million share purchase proceeds received on April 3, 2018, as a result of our new Bristol-Myers Squibb collaboration.

"Nektar begins 2018 in a very strong position with a major collaboration with Bristol-Myers Squibb for NKTR-214 and key advancements in our immuno-oncology and immunology pipeline," said Howard W. Robin, President and CEO of Nektar. "The PIVOT study of NKTR-214 in combination with nivolumab continues to enroll patients and we are exceptionally pleased that the preliminary data from PIVOT was accepted for an oral presentation at this year's ASCO Meeting. We initiated two new clinical studies this quarter, the first with our novel I-O combination of NKTR-262 and NKTR-214 and the second with our autoimmune disease candidate, NKTR-358. Based on positive preclinical results, we entered into a clinical collaboration with Takeda to evaluate NKTR-214 with their TAK-659, a SYK/FLT inhibitor. Finally, in the area of pain, we plan to submit our NDA filing for NKTR-181 this month."

Revenue in the first quarter of 2018 was $38.0 million as compared to $24.7 million in the first quarter of 2017. Revenue in the first quarter of 2018 was higher primarily because of the recognition of $10.0 million received from Shire for the approval of Adynovi in Europe.

Total operating costs and expenses in the first quarter of 2018 were $124.8 million as compared to $79.2 million in the first quarter of 2017. Total operating costs and expenses increased primarily as a result of increased research and development (R&D) expense.

R&D expense in the first quarter of 2018 was $99.4 million as compared to $61.1 million for the first quarter of 2017. R&D expense was higher in the first quarter 2018 as compared to the same period in 2017 primarily because of expenses for our pipeline programs, including the completion of Phase 3 clinical studies for NKTR-181, Phase 1/2 clinical studies of NKTR-214 and NKTR-358, initiation of the Phase 1 study of NKTR-262 in combination with NKTR-214 and IND-enabling activities for NKTR-255.

General and administrative expense was $18.7 million in the first quarter of 2018 as compared to $12.0 million in the first quarter of 2017 and increased primarily due to increased stock based compensation.

In the first quarter of 2018, net loss was $95.8 million, or $0.60 loss per share as compared to net loss of $63.9 million, or $0.42 loss per share in the first quarter of 2017.

2018 Business Highlights

- In May, Nektar began dosing patients with systemic lupus erythematosus in a Phase 1b multiple ascending dose study of NKTR-358, a first-in-class regulatory T cell stimulator, designed to correct the underlying immune system dysfunction found in patients with immune disorders.
- In April, Nektar announced a new clinical collaboration agreement with Takeda to evaluate NKTR-214 in combination with TAK-659, a dual SYK and FLT-3 inhibitor in liquid and solid tumors with the first of these studies expected to begin in the second half of 2018 in patients with Non-Hodgkin Lymphoma.
- In April, Nektar presented positive preclinical data for its immuno-oncology programs at the 2018 AACR Annual Meeting. Preclinical data presented by Nektar researchers and collaborators demonstrate how NKTR-214 synergizes with multiple modalities including TLRs, HDAC and ACT, highlighting the potential of NKTR-214 as a backbone therapy in immuno-oncology.
- In April, Nektar began dosing patients in the REVEAL Phase 1/2 study, which will evaluate the safety and efficacy of NKTR-262, a novel toll-like receptor agonist, in combination with NKTR-214. This novel-novel combination is designed to engage both the innate and adaptive immune response to fight cancer and may ultimately provide another option for patients with many types of advanced or metastatic solid tumor cancers.
- In February, Nektar and Bristol-Myers Squibb entered into a global development and commercialization agreement to evaluate the full potential of NKTR-214 plus Opdivo® (nivolumab) in more than 20 indications in 9 tumor types including melanoma, renal cell carcinoma, non-small cell lung cancer, bladder and triple negative breast cancer.

The company also announced upcoming presentations at the following scientific congresses during the second quarter of 2018:

Treg Directed Therapy for Autoimmune Disorders Meeting, Boston, MA:

- **Preclinical Data Presentation:** *"NKTR-358: An IL-2 Pathway Agonist that Selectively Expands and Activates Regulatory T cells for the Treatment of Allergy and Autoimmune Disease"*
    - **Presenter:** Jonathan Zalevsky, Ph.D., Nektar Therapeutics
    - **Session:** Enhanced Treg-based therapy with the use of IL-2
    - **Date:** Wednesday, May 23, 2018, 3:40 p.m. Eastern Daylight Time

3rd Annual Advances in Immuno-Oncology Congress, London, U.K.:

- **Presentation:** *"Accessing The Potential Of An Immunotherapeutic Agent"*
    - **Presenter:** Jonathan Zalevsky, Ph.D., Nektar Therapeutics
    - **Session:** Translational Immuno-Oncology
    - **Date:** Thursday, May 24, 2018, 5:40 p.m. British Summer Time

American Society for Clinical Oncology (ASCO) 2018 Annual Meeting, Chicago, IL:

- **Oral Presentation:** "*NKTR-214 (CD122-biased agonist) plus nivolumab in patients with advanced solid tumors: Preliminary phase 1/2 results of PIVOT".*
    - **Abstract #3006**
    - **Presenter:** Dr. Adi Diab, Assistant Professor, Department of Melanoma Medical Oncology, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center, Houston, Texas
    - **Session:** Developmental Therapeutics - Immunotherapy
    - **Date:**Saturday, June 2, 2018, 3:00 p.m. - 6:00 p.m. Central Daylight Time

- **Abstract #2567:** "*TAK-659 in Combination with NKTR-214 and anti-PD-1 Therapy Leads to Complete and Sustained Tumor Regression and Immune Memory In Pre-Clinical Syngeneic Models*", Huck, J., et al.
    - **Session:** Developmental Therapeutics - Clinical Pharmacology and Experimental Therapeutics
    - **Date:**Monday, June 4, 2018, 8:00 a.m. - 11:30 a.m. Central Daylight Time

- **Abstract #3085:***"Efficacy and immune modulation by BXCL701 a dipeptidyl peptidase inhibitor, NKTR-214 a CD122-biased immune agonist with PD1 blockade in murine pancreatic tumors",* Rastelli, L., et al.
    - **Session:** Developmental Therapeutics - Immunotherapy
    - **Date:**Monday, June 4, 2018, 8:00 a.m. - 11:30 a.m. Central Daylight Time

- **Abstract #5582:** "*Efficacy and immune modulation of the tumor microenvironment in murine ovarian tumor with the PARP inhibitor rucaparib and CD122-biased immune agonist NKTR-214*", Simmons, A., et al.
    - **Session:** Gynecologic Cancer
    - **Date:**Monday, June 4, 2018, 1:15 p.m. - 4:45 p.m. Central Daylight Time

- **Abstract #TPS3115:** "*PROPEL: A phase 1/2 trial of NKTR-214 (CD122-biased agonist) combined with anti-PD-1 (pembrolizumab) or anti-PD-L1 (atezolizumab) in patients (pts) with advanced solid tumors*", Vaena, D., et al.
    - **Session:** Developmental Therapeutics - Immunotherapy
    - **Date:**Monday, June 4, 2018, 8:00 a.m. - 11:30 a.m. Central Daylight Time

- **Abstract #TPS1111:** "*ATTAIN: Phase 3 study of etirinotecan pegol (EP) vs. treatment of physician's choice (TPC) in patients (pts) with metastatic breast cancer (MBC) who have stable brain metastases (BM) previously treated with an anthracycline, a taxane, and capecitabine (ATC)*", Tripathy, D., et al.
    - **Session:** Breast Cancer - Metastatic
    - **Date:**Saturday, June 2, 2018, 8:00 a.m. - 11:30 a.m. Central Daylight Time

College on Problems of Drug Dependence 80th Annual Scientific Meeting (2018), San Diego, CA:

- **Oral Presentation:** *"Assessment of Drug Abuse-Related Events with MADDERS in SUMMIT-07: A Phase-3 Study of NKTR-181 in Patients with Moderate to Severe Chronic Low-Back Pain"*
    - **Abstract #76**
    - **Presenter:** Ryan Lanier, Ph.D., Analgesic Solutions
    - **Session:** The Pain and the Strain Comes Mainly from the Brain
    - **Date:**Wednesday, June 13, 2018, 1:30 p.m. - 1:45 p.m. Pacific Daylight Time

- **Oral Presentation:***"Neuropharmacodynamic Profile of NKTR-181: Correlation to Low Abuse Potential"*
    - **Abstract #335**

- **Presenter:** Laurie Vanderveen, Ph.D., Nektar Therapeutics
- **Session:** Basically Opioids
- **Date:**Tuesday, June 12, 2018, 10:15 a.m. - 10:30 a.m. Pacific Daylight Time

- **Abstract #168**: *"NKTR-181 demonstrates low abuse potential in recreational opioid users in two double-blind, randomized crossover human abuse potential studies"*, Henningfield, J., et al.
  - **Session:** Abuse Liability
  - **Date:**Thursday, June 14, 2018, 12:00 p.m. - 2:00 p.m. Pacific Daylight Time

Conference Call to Discuss First Quarter 2018 Financial Results
Nektar management will host a conference call to review the results beginning at 5:00 p.m. Eastern Time/2:00 p.m. Pacific Time, Thursday, May 10, 2018.

This press release and a live audio-only Webcast of the conference call can be accessed through a link that is posted on the home page and Investors section of the Nektar website: http://ir.nektar.com/index.cfm. The web broadcast of the conference call will be available for replay through Monday, June 11, 2018.

To access the conference call, follow these instructions:
Dial: (877) 881.2183 (U.S.); (970) 315.0453 (international)
Passcode: 2379326 (Nektar Therapeutics is the host)

In the event that any non-GAAP financial measure is discussed on the conference call that is not described in the press release, or explained on the conference call, related information will be made available on the Investors page at the Nektar website as soon as practical after the conclusion of the conference call.

About Nektar
Nektar Therapeutics is a research-based development stage biopharmaceutical company whose mission is to discover and develop innovative medicines to address the unmet medical needs of patients. Our R&D pipeline of new investigational medicines includes treatments for cancer, auto-immune disease and chronic pain. We leverage Nektar's proprietary and proven chemistry platform in the discovery and design of our new therapeutic candidates. Nektar is headquartered in San Francisco, California, with additional operations in Huntsville, Alabama and Hyderabad, India. Further information about the company and its drug development programs and capabilities may be found online at http://www.nektar.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains uncertain or forward-looking statements which can be identified by words such as: "expect," "plan," "may," "will," "design," "develop," "enable" and similar references to future periods. Examples of forward-looking statements include, among others, statements we make regarding the potential therapeutic benefits of and future development plans for our products (including NKTR-214, NKTR-181, NKTR-358, NKTR-262 and NKTR-255) and the timing for filing a new drug application, "NDA". Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions and are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results may differ materially from those indicated in the forward-looking statements and you should not rely on such statements. Important factors that could cause our actual results to differ materially from those indicated in the forward-looking statements include: (i) clinical study outcomes remain very unpredictable and it is possible that a clinical study could fail even after positive interim data is observed; (ii) the data package required for filing and approval of an NDA to the FDA is very uncertain and difficult to predict due to broad FDA regulatory discretion, and changing FDA regulatory guidelines; (iii) regulations concerning and controlling access to opioid-based pharmaceuticals are strict and it is difficult to predict which scheduling category will apply to NKTR-181 if regulatory approval is achieved; (iv) patents may not issue from our patent applications for our drug candidates, patents that have issued may not be enforceable, or additional intellectual property licenses from third parties may be required; and (v) certain other important risks and uncertainties set forth in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 1, 2018. Any forward-looking statement made by us in this press release is based only on information currently available to us and speaks only as of the date on which it is made. We undertake no obligation to update any forward-looking statement.

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NEKTAR THERAPEUTICS
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)
(Unaudited)

ASSETS	March 31, 2018	December 31, 2017 (1)
Current assets:		
Cash and cash equivalents	$ 34,805	$ 4,762
Short-term investments	261,854	291,370
Accounts receivable, net	15,607	5,014
Inventory	10,675	10,726
Other current assets	13,074	14,948
Total current assets	336,015	326,820
Long-term investments	37,157	57,088
Property, plant and equipment, net	46,328	47,463
Goodwill	76,501	76,501
Other assets	789	994
Total assets	$ 496,790	$ 508,866
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 11,375	$ 4,782
Accrued compensation	15,130	8,263
Accrued clinical trial expenses	19,790	9,461
Other accrued expenses	10,676	10,064
Interest payable	4,090	4,198
Deferred revenue, current portion	19,531	18,949
Other current liabilities	105	446
Total current liabilities	80,697	56,163
Senior secured notes, net	245,643	245,207
Liability related to sale of future royalties, net	92,846	94,655
Deferred revenue, less current portion	12,808	19,021
Other long-term liabilities	6,513	5,992
Total liabilities	438,507	421,038
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	-	-
Common stock	16	15
Capital in excess of par value	2,262,219	2,207,865
Accumulated other comprehensive loss	(2,796)	(2,111)
Accumulated deficit	(2,201,156)	(2,117,941)
Total stockholders' equity	58,283	87,828
Total liabilities and stockholders' equity	$ 496,790	$ 508,866

(1) The consolidated balance sheet at December 31, 2017 has been derived from the audited financial statements at that date but does not include all of the information and notes required by generally accepted accounting principles in the United States for complete financial statements.

NEKTAR THERAPEUTICS
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share information)
(Unaudited)

	Three Months Ended March 31, 2018	2017
Revenue:		
Product sales	$ 6,295	$ 4,756
Royalty revenue	11,076	7,217
Non-cash royalty revenue related to sale of future royalties	6,920	6,663
License, collaboration and other revenue	13,727	6,092
Total revenue	38,018	24,728
Operating costs and expenses:		
Cost of goods sold	6,646	6,131
Research and development	99,424	61,058
General and administrative	18,687	11,976

Total operating costs and expenses	124,757	79,165
Loss from operations	(86,739)	(54,437)
Non-operating income (expense):		
Interest expense	(5,340)	(5,402)
Non-cash interest expense on liability related to sale of future royalties	(5,019)	(4,552)
Interest income and other income (expense), net	1,571	658
Total non-operating expense, net	(8,788)	(9,296)
Loss before provision for income taxes	(95,527)	(63,733)
Provision for income taxes	265	133
Net loss	$ (95,792)	$ (63,866)
Basic and diluted net loss per share	$ (0.60)	$ (0.42)
Weighted average shares outstanding used in computing basic and diluted net loss per share	160,884	153,666

NEKTAR THERAPEUTICS
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2018	2017
Cash flows from operating activities:		
Net loss	$ (95,792)	$ (63,866)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash royalty revenue related to sale of future royalties	(6,920)	(6,663)
Non-cash interest expense on liability related to sale of future royalties	5,019	4,552
Stock-based compensation	19,949	8,184
Depreciation and amortization	2,541	4,033
Other non-cash transactions	(370)	(731)
Changes in operating assets and liabilities:		
Accounts receivable, net	151	14,113
Inventory	51	(1,907)
Other assets	1,853	2,134
Accounts payable	6,492	4,117
Accrued compensation	6,867	(6,817)
Accrued clinical trial expenses	10,329	(515)
Other accrued expenses	605	1,798
Interest payable	(108)	(108)
Deferred revenue	(3,678)	9,619
Other liabilities	545	(2,509)
Net cash used in operating activities	(52,466)	(34,566)
Cash flows from investing activities:		
Purchases of investments	-	(75,857)
Maturities of investments	37,232	58,053
Sales of investments	11,963	8,823
Purchases of property, plant and equipment	(985)	(4,089)
Net cash provided by (used in) investing activities	48,210	(13,070)
Cash flows from financing activities:		
Payment of capital lease obligations	-	(613)
Proceeds from shares issued under equity compensation plans	34,352	11,792
Net cash provided by financing activities	34,352	11,179
Effect of exchange rates on cash and cash equivalents	(53)	297
Net increase (decrease) in cash and cash equivalents	30,043	(36,160)
Cash and cash equivalents at beginning of period	4,762	59,640
Cash and cash equivalents at end of period	$ 34,805	$ 23,480
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 4,952	$ 5,067

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