Nektar Therapeutics Reports Financial Results for the First Quarter of 2019

May 8, 2019

SAN FRANCISCO, May 8, 2019 /PRNewswire/ -- Nektar Therapeutics (Nasdaq: NKTR) today reported its financial results for the first quarter ended March 31, 2019.

Cash and investments in marketable securities at March 31, 2019 were approximately $1.8 billion as compared to $1.9 billion at December 31, 2018.

"Nektar continues to advance our immuno-oncology and immunology pipeline with clinical trials initiating for multiple drug candidates across multiple indications," said Howard W. Robin, President and CEO of Nektar. "We are working with our partner, Bristol-Myers Squibb, to execute on our broad joint development program for bempegaldesleukin in combination with nivolumab, with registrational trials in melanoma, RCC, urothelial and non-small cell lung cancer underway and additional trials planned to begin in the coming months."

"NKTR-181 is under review with the FDA and we are planning for a potential launch later this year," continued Robin. "With respect to NKTR-358, we will report the first data for this exciting drug candidate in an oral presentation at the EULAR Congress in June and our multiple-ascending dose trial in lupus patients is continuing. With our partner Lilly, we continue to advance development of NKTR-358 with two new Phase 1b studies in additional auto-immune disorders planned to start in 2019. We are also completing our IND-enabling activities for our next immuno-oncology candidate, NKTR-255, which activates the IL-15 pathway."

Revenue in the first quarter of 2019 was $28.2 million as compared to $38.0 million in the first quarter of 2018. Revenue in the first quarter of 2019 was lower primarily due to the recognition of $10.0 million received in the first quarter of 2018 from Takeda for the approval of Adynovi® in Europe.

Total operating costs and expenses in the first quarter of 2019 were $148.9 million as compared to $124.8 million in the first quarter of 2018. 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 2019 was $118.5 million as compared to $99.4 million for the first quarter of 2018. R&D expense was higher in the first quarter of 2019 as compared to the same period in 2018 primarily because of expenses for our pipeline programs, including the continued development of bempegaldesleukin in Phase 2 and registrational studies and related manufacturing costs, costs related to Phase 1 clinical studies of NKTR-358 and IND-enabling activities for NKTR-255.

General and administrative expense was $25.0 million in the first quarter of 2019 as compared to $18.7 million in the first quarter of 2018 and increased primarily due to costs related to commercialization readiness activities for NKTR-181 and increased non-cash stock-based compensation.

In the first quarter of 2019, net loss was $118.5 million, or $0.68 loss per share as compared to net loss of $95.8 million, or $0.60 loss per share in the first quarter of 2018.

2019 Business Highlights

- In April, Nektar presented positive preclinical data on its immuno-oncology pipeline candidates, bempegaldesleukin and NKTR-255, an IL-15 receptor agonist, at the 2019 AACR Annual Meeting.
- In March, Nektar presented preliminary immune activation, safety and clinical activity data from the ongoing dose-escalation stage of the REVEAL study at the 2019 ASCO-SITC Meeting. The REVEAL Phase 1/2 study is evaluating the safety and efficacy of NKTR-262, a novel TLR agonist, in combination with bempegaldesleukin.
- In February, Nektar presented clinical data from first-line Stage IV urothelial carcinoma patients enrolled in the PIVOT-02 study of bempegaldesleukin with nivolumab at the 2019 ASCO Genitourinary Cancers Symposium.

The company also announced upcoming presentations at the following scientific congresses during the second quarter of 2019:

4th Drug Discovery Nexus, Boston, MA:

- **Presentation:***"Harnessing cytokines to develop immune therapeutic agents"*
  - **Presenter:** Loui Madakamutil, Ph.D., Nektar Therapeutics
  - **Date:**Friday, May 17, 2019, 9:30 a.m. Eastern Daylight Time

4th Annual Advances in Immuno-Oncology Congress 2019, London, U.K.:

- **Presentation:** *"Bempegaldesleukin (NKTR-214): Targeting the IL-2 Pathway for Immuno-Oncology Applications"*

- **Presenter:**Jonathan Zalevsky, Ph.D., Nektar Therapeutics
- **Session:** Immuno-Oncology Therapeutic Approaches, Clinical Research & Clinical Trials
- **Date:**Tuesday, May 21, 2019, 16:30 British Summer Time

American Society for Clinical Oncology (ASCO) 2019 Annual Meeting, Chicago, IL:

- **Oral Abstract # 11010:***"Pilot study of bempegaldesleukin (NKTR-214) and nivolumab in patients with sarcomas"*
  - **Presenter:**Sandra D'Angelo, M.D., Memorial Sloan-Kettering Cancer Center
  - **Session:** Clinical Science Symposium: Emerging Combinations in Sarcoma Immunotherapy
  - **Date:**Monday, June 3, 2019, 11:30 a.m. - 1:00 p.m. Central Daylight Time
- **Poster #228/Abstract # 2584:***"Overcoming genetically-based resistance mechanisms to PD-1 blockade",* Torrejon, D., et al.
  - **Session:** Developmental Immunotherapy and Tumor Immunobiology
  - **Date:**Saturday, June 1, 2019, 8:00 a.m. - 11:00 a.m. Central Daylight Time
- **Poster #267/Abstract # 2623:***"Baseline tumor immune signatures associated with response to bempegaldesleukin (NKTR-214) and nivolumab"*, Hurwitz, M., et al.
  - **Session:** Developmental Immunotherapy and Tumor Immunobiology
  - **Date:**Saturday, June 1, 2019, 8:00 a.m. - 11:00 a.m. Central Daylight Time
- **Poster #416b/Abstract # TPS4595:** *"A phase III randomized open label study comparing bempegaldesleukin (NKTR-214) plus nivolumab to sunitinib or cabozantinib (investigator's choice) in patients with previously untreated advanced renal cell carcinoma",* Tannir, N., et al.
  - **Session:** Genitourinary (Nonprostate) Cancer
  - **Date:**Monday, June 3, 2019, 1:15 p.m. - 4:15 p.m. Central Daylight Time
- **Poster 168b/Abstract # TPS9601:***"A phase III, randomized, open-label study of bempegaldesleukin (NKTR-214) plus nivolumab (NIVO) versus NIVO monotherapy in patients (pts) with previously untreated, unresectable or metastatic melanoma (MEL)",* Khushalani, N., et al.
  - **Session:** Melanoma/Skin Cancers
  - **Date:**Monday, June 3, 2019, 1:15 p.m. - 4:15 p.m. Central Daylight Time

Pharmaceutical & Bioscience Society Symposium: Advances in Immuno-Oncology, Foster City, CA:

- **Presentation:** *"Bempegaldesleukin (NKTR-214), a first-in-class, CD122-preferential IL-2 pathway agonist"*
  - **Presenter:**Willem Overwijk, Ph.D., Nektar Therapeutics
  - **Date:**Tuesday, June 11, 2019, 8:45 a.m. Pacific Daylight Time

24th Congress of European Hematology Association (EHA), Amsterdam, Netherlands:

- **Abstract # PS1208:** *"Effects Of NKTR-255, A Polymer Conjugated Human IL-15, on Efficacy of CD19 CAR T Cell Immunotherapy in a Preclinical Lymphoma Model"*
  - **Presenter:**Cassie K. Chou, M.D., Ph.D., Fred Hutchinson Cancer Research Center
  - **Session:** Gene therapy, cellular immunotherapy and vaccination – Biology & Transitional Research
  - **Date:**Saturday, June 15, 2019, 17:30 – 19:00 Central European Summer Time
  - **Poster Pitch:**Saturday, June 15, 2019, 16:30 – 16:45 Central European Summer Time
  - **Location:** Hall G106

Annual European Congress of Rheumatology (EULAR) 2019, Madrid, Spain:

- **Abstract # OP0195:** *"Selective Expansion of Regulatory T-Cells in Humans by a Novel IL-2 Conjugate T-reg Stimulator, NKTR-358, Being Developed for the Treatment of Autoimmune Diseases"*
  - **Presenter:**Brian Kotzin, M.D., Nektar Therapeutics
  - **Session:** Genetics, epigenetics and immunity
  - **Date:**Thursday, June 13, 2019, 11:15 Central European Summer Time

Conference Call to Discuss First Quarter 2019 Financial Results
Nektar management will host a conference call to review the results beginning at 5:00 p.m. Eastern Daylight Time/2:00 p.m. Pacific Daylight Time, Wednesday, May 8, 2019.

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: https://ir.nektar.com/. The web broadcast of the conference call will be available for replay through Monday, June 10, 2019.

To access the conference call, follow these instructions:

Dial: (877) 881-2183 (U.S.); (970) 315-0453 (international)
Passcode: 8249707 (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, autoimmune disease and chronic pain. We leverage our 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 Nektar and its drug development programs and capabilities may be found online at 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: "advance," "planned," "preparing," "potential," "continue," "may," "will" 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 investigational products [including bempegaldesleukin ("bempeg"), NKTR-181, NKTR-358, NKTR-262 and NKTR-255], the timing of a potential launch for NKTR-181, and the results of clinical trials. 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) the timing of the commencement or end of clinical studies and the availability of clinical data may be delayed or unsuccessful due to regulatory delays, slower than anticipated patient enrollment, manufacturing challenges, changing standards of care, evolving regulatory requirements, clinical trial design, clinical outcomes, and enrollment competition; (ii) the timing and probability of regulatory approval, if any, for NKTR-181 is uncertain and difficult to predict; (iii) scientific discovery of new medical breakthroughs is an inherently uncertain process and the future success of applying our technology platform to drug candidates [such as bempegaldesleukin ("bempeg"), NKTR-262, NKTR-358, and NKTR-255] is therefore highly uncertain and unpredictable and one or more of these programs may fail; (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 Nektar's Annual Report on Form 10-K for the year ended December 31, 2018 filed with the Securities and Exchange Commission on March 1, 2019. 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.

Adynovi is a registered trademark of Baxalta Incorporated.

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

ASSETS	March 31, 2019	December 31, 2018[1]
Current assets:		
Cash and cash equivalents	$ 106,752	$ 194,905
Short-term investments	1,281,913	1,140,445
Accounts receivable	42,894	43,213
Inventory	11,778	11,381
Advance payments to contract manufacturers	27,425	26,450
Other current assets	19,352	21,293
Total current assets	1,490,114	1,437,687
Long-term investments	455,867	582,889
Property, plant and equipment, net	58,158	48,851
Operating lease right-of-use assets	83,475	-
Goodwill	76,501	76,501
Other assets	2,367	4,244

Total assets	$ 2,166,482	$ 2,150,172

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Accounts payable	$ 11,012	$ 5,854
Accrued compensation	18,371	9,937
Accrued contract manufacturing expenses	21,384	23,841
Accrued clinical trial expenses	17,496	14,700
Other accrued expenses	14,624	9,580
Interest payable	4,090	4,198
Operating lease liabilities, current portion	1,649	-
Deferred revenue, current portion	11,092	13,892
Total current liabilities	99,718	82,002
Senior secured notes, net	247,386	246,950
Operating lease liabilities, less current portion	95,024	-
Liability related to the sale of future royalties, net	80,837	82,911
Deferred revenue, less current portion	9,340	10,744
Other long-term liabilities	666	9,990
Total liabilities	532,971	432,597
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	-	-
Common stock	17	17
Capital in excess of par value	3,178,773	3,147,925
Accumulated other comprehensive loss	(2,716)	(6,316)
Accumulated deficit	(1,542,563)	(1,424,051)
Total stockholders' equity	1,633,511	1,717,575
Total liabilities and stockholders' equity	$ 2,166,482	$ 2,150,172

(1) The consolidated balance sheet at December 31, 2018 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,	
	2019	2018
Revenue:		
Product sales	$ 4,398	$ 6,295
Royalty revenue	11,390	11,076
Non-cash royalty revenue related to sale of future royalties	8,230	6,920
License, collaboration and other revenue	4,204	13,727
Total revenue	28,222	38,018
Operating costs and expenses:		
Cost of goods sold	5,440	6,646
Research and development	118,463	99,424
General and administrative	25,006	18,687
Total operating costs and expenses	148,909	124,757
Loss from operations	(120,687)	(86,739)
Non-operating income (expense):		
Interest expense	(5,226)	(5,340)
Non-cash interest expense on liability related to sale of future royalties	(6,065)	(5,019)
Interest income and other income (expense), net	12,483	1,571
Total non-operating income (expense), net	1,192	(8,788)

Loss before provision for income taxes	(119,495)	(95,527)
Provision (benefit) for income taxes	(983)	265
Net loss	$ (118,512)	$ (95,792)
Basic and diluted net loss per share	$ (0.68)	$ (0.60)
Weighted average shares outstanding used in computing basic and diluted net loss per share	173,859	160,884

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

	Three Months Ended March 31,	
	2019	2018
Cash flows from operating activities:		
Net loss	$ (118,512)	$ (95,792)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash royalty revenue related to sale of future royalties	(8,230)	(6,920)
Non-cash interest expense on liability related to sale of future royalties	6,065	5,019
Stock-based compensation	25,385	19,949
Depreciation and amortization	3,077	2,541
Accretion of discounts, net and other non-cash transactions	(4,303)	(370)
Changes in operating assets and liabilities:		
Accounts receivable	319	151
Inventory	(397)	51
Other assets	4,209	1,853
Accounts payable	5,156	6,492
Accrued compensation	8,434	6,867
Other accrued expenses	774	10,826
Deferred revenue	(4,204)	(3,678)
Other liabilities	1,332	545
Net cash used in operating activities	(80,895)	(52,466)
Cash flows from investing activities:		
Purchases of investments	(368,739)	-
Maturities of investments	362,249	37,232
Sales of investments	-	11,963
Purchases of property, plant and equipment	(5,648)	(985)
Net cash provided by (used in) investing activities	(12,138)	48,210
Cash flows from financing activities:		
Proceeds from shares issued under equity compensation plans	4,894	34,352
Net cash provided by financing activities	4,894	34,352
Effect of exchange rates on cash and cash equivalents	(14)	(53)
Net increase (decrease) in cash and cash equivalents	(88,153)	30,043
Cash and cash equivalents at beginning of period	194,905	4,762
Cash and cash equivalents at end of period	$ 106,752	$ 34,805
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 4,805	$ 4,952

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