Nektar Therapeutics Reports Financial Results for the Second Quarter of 2019

August 8, 2019

Company to Host Conference Call with Analysts to Review Financial Results and Provide Update on the NKTR-214 (bempegaldesleukin) Program

SAN FRANCISCO, Aug. 8, 2019 /PRNewswire/ -- Nektar Therapeutics (Nasdaq: NKTR) today reported its financial results for the second quarter ended June 30, 2019.

Cash and investments in marketable securities at June 30, 2019 were $1.8 billion as compared to $1.9 billion at December 31, 2018.

"Nektar is making good progress advancing our multiple programs in immuno-oncology, immunology and pain," said Howard W. Robin, President and CEO of Nektar. "With our partner Bristol-Myers Squibb, although we've experienced some delays, we are working to finalize the development program for bempegaldesleukin in combination with nivolumab in a number of tumor types and which are designed to support registration for this unique I-O doublet. We have a number of registrational trials already started and we recently received a breakthrough designation from FDA for bempeg and nivo in the setting of first-line untreated metastatic melanoma. Our partner Eli Lilly will be initiating several new studies later this year for NKTR-358, our T regulatory stimulator candidate. These studies will expand the program with additional indications beyond lupus. We recently filed an IND with the FDA for NKTR-255, our IL-15 agonist, and will initiate our first-in-human clinical study this quarter in patients with relapsed, refractory NHL and in patients with multiple myeloma."

Nektar is hosting a conference call with analysts and investors today on which it will discuss quarterly results. On the call, the company will provide a specific update and discussion on its bempegaldesleukin clinical development program, including recent developments related to the manufacturing of bempegaldesleukin.

Revenue in the second quarter of 2019 was $23.3 million as compared to $1.088 billion in the second quarter of 2018. Year-to-date revenue for 2019 was $51.5 million as compared to $1.126 billion in the first half of 2018. Revenue was lower in the second quarter and first half of 2019 as compared to the same periods in 2018 primarily because of the recognition of $1.06 billion of license revenue from the Bristol-Myers Squibb collaboration agreement in the second quarter of 2018.

Total operating costs and expenses in the second quarter of 2019 were $134.3 million as compared to $114.1 million in the second quarter of 2018. Total operating costs and expenses in the first half of 2019 were $283.2 million as compared to $238.9 million in the first half 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 second quarter of 2019 was $106.7 million as compared to $88.3 million in the second quarter of 2018. For the first half of 2019, R&D expense was $225.1 million as compared to $187.8 million in the first half of 2018. R&D expense was higher in the second quarter and first half of 2019 as compared to the same periods 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. These increases were partially offset by cost decreases related to the NKTR-181 New Drug Application and NKTR-181 pre-commercial manufacturing which were higher during the second quarter and first half of 2018.

General and administrative (G&A) expense was $22.6 million in the second quarter of 2019 as compared to $20.3 million in the second quarter of 2018. G&A expense in the first half of 2019 was $47.6 million as compared to $38.9 million in the first half of 2018. G&A expense was higher in the second quarter and first half of 2019 as compared to the same periods in 2018 primarily due to costs related to commercialization readiness activities for NKTR-181 and increased non-cash stock-based compensation.

Net loss in the second quarter of 2019 was $109.9 million or $0.63 basic and diluted loss per share as compared to a net income of $971.5 million or $5.33 diluted earnings per share in the second quarter of 2018. Net loss in the first half of 2019 was $228.4 million or $1.31 basic and diluted loss per share as compared to a net income of $875.7 million or $4.91 diluted earnings per share in the first half of 2018.

Second Quarter 2019 and Recent Business Highlights

- In August, the FDA granted Breakthrough Therapy Designation for bempegaldesleukin in combination with Opdivo (nivolumab) for the treatment of patients with previously untreated unresectable or metastatic melanoma.
- In July, for NKTR-181, Nektar received a General Advice Letter from FDA that stated that it is postponing product-specific advisory committee meetings for opioid analgesics, including the one previously scheduled for August 21, 2019 to discuss the NDA for the NKTR-181 product, while the agency continues to consider a number of scientific and policy issues relating to this class of drugs. The FDA indicated that it will continue to review the NDA for NKTR-181 according to the existing Prescription Drug User Fee Act ("PDUFA") timeline; however, because of the postponed Advisory Committee

Meeting, it is possible the agency may not be able to meet the PDUFA goal date of August 29, 2019.

- In June, Nektar presented data from a first-in-human Phase 1a study evaluating single-ascending doses of NKTR-358, supporting development of the candidate as a first-in-class T regulatory cell stimulator for the treatment of autoimmune and other chronic inflammatory conditions.
- In June, Nektar presented data for NKTR-181 at the 81st Annual Scientific Meeting of the College on Problems of Drug Dependence. The data presented identified low rates of withdrawal and a low risk of abuse potential, diversion or addiction associated with NKTR-181 in Phase 3 trials according to the MADDERS® system, the first standardized system for discerning abuse-related events.
- In June, Nektar presented biomarker and clinical data from the ongoing Phase 2 PIVOT-02 study for bempegaldesleukin in combination with Opdivo (nivolumab) at the 2019 ASCO Annual Meeting. Clinical data presented included 12 month follow-up for the Stage 4 first-line melanoma patient cohort and showed a deepening and durability of response over time. Registrational studies in melanoma, renal cell carcinoma and urothelial cancer are currently recruiting patients.
- In May, Nektar announced formation of Inheris Biopharma, Inc., a wholly-owned subsidiary responsible for launch preparation and commercialization for NKTR-181, a novel, first-in-class, investigational opioid molecule. NKTR-181 is currently under review with the U.S. Food and Drug Administration (FDA).

The company also announced the following upcoming presentations during the second half of 2019:

CAR-TCR Summit, Boston, MA:

- **Presentation:***"Utilizing Next Generation Cytokines to Enhance Efficacy and Durability of CAR-Ts"*
  - **Presenter:**Mario Marcondes, M.D., Nektar Therapeutics
  - **Session:** Enhancing Efficacy with Combinations
  - **Date and Time:**September 11, 2019, 6:18 – 6:48 p.m. EDT

Oxford Global 2nd Annual Advances In Immuno-Oncology USA Congress, San Diego, CA:

- **Presentation:***"Harnessing Potent Cytokine Agonist Pathways by Polymer Engineering to Develop Novel Immune Therapeutic Agents"*
  - **Presenter:** Loui Madakamutil, Ph.D., Nektar Therapeutics
  - **Date and Time:**October 9, 2019, 12:00 – 12:30 p.m. PDT

American Conference on Pharmacometrics (ACoP) 2019, Orlando, FL:

- **Poster Title:***"NKTR-262 Released Below Quantifiable Levels of TLR 7/8 Agonist in Human Plasma in Phase 1b/2 Clinical Study as Predicted A-Priori by PK Modeling and Scaling to Humans"*, Bhasi, K., et al.
  - **Date:**October 20 – 23, 2019

Conference Call to Discuss Second Quarter 2019 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 today, Thursday, August 8, 2019.

This press release and a live 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/. The web broadcast of the conference call will be available for replay through Monday, September 9, 2019.

To access the conference call, follow these instructions:

Dial: (877) 881-2183 (U.S.); (970) 315-0453 (international)
Passcode: 2879328 (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 Therapeutics

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: "advance," "planned," "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-214"), 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-214"), 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 9, 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.

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

ASSETS	June 30, 2019	December 31, 2018[1]
Current assets:		
Cash and cash equivalents	$ 85,424	$ 194,905
Short-term investments	1,429,955	1,140,445
Accounts receivable	37,299	43,213
Inventory	13,188	11,381
Advance payments to contract manufacturers	17,738	26,450
Other current assets	13,213	21,293
Total current assets	1,596,817	1,437,687
Long-term investments	276,305	582,889
Property, plant and equipment, net	65,453	48,851
Operating lease right-of-use assets	82,177	-
Goodwill	76,501	76,501
Other assets	2,400	4,244
Total assets	$ 2,099,653	$ 2,150,172
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 9,346	$ 5,854
Accrued compensation	19,710	9,937
Accrued clinical trial expenses	29,540	14,700
Accrued contract manufacturing expenses	23,159	23,841
Other accrued expenses	13,830	9,580
Interest payable	4,144	4,198

Operating lease liabilities, current portion	3,749	-
Deferred revenue, current portion	9,892	13,892
Total current liabilities	113,370	82,002
Senior secured notes, net	247,821	246,950
Operating lease liabilities, less current portion	94,822	-
Liability related to the sale of future royalties, net	77,813	82,911
Deferred revenue, less current portion	8,029	10,744
Other long-term liabilities	643	9,990
Total liabilities	542,498	432,597
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	-	-
Common stock	17	17
Capital in excess of par value	3,210,398	3,147,925
Accumulated other comprehensive loss	(788)	(6,316)
Accumulated deficit	(1,652,472)	(1,424,051)
Total stockholders' equity	1,557,155	1,717,575
Total liabilities and stockholders' equity	$ 2,099,653	$ 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 June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenue:				
Product sales	$ 4,346	$ 5,863	$ 8,744	$ 12,158
Royalty revenue	7,343	8,563	18,733	19,639
Non-cash royalty revenue related to sale of future royalties	9,091	9,045	17,321	15,965
License, collaboration and other revenue	2,535	1,064,246	6,739	1,077,973
Total revenue	23,315	1,087,717	51,537	1,125,735
Operating costs and expenses:				
Cost of goods sold	5,018	5,522	10,458	12,168
Research and development	106,686	88,334	225,149	187,758
General and administrative	22,581	20,261	47,587	38,948
Total operating costs and expenses	134,285	114,117	283,194	238,874
Income (loss) from operations	(110,970)	973,600	(231,657)	886,861
Non-operating income (expense):				
Interest expense	(5,231)	(5,385)	(10,457)	(10,725)
Non-cash interest expense on liability related to sale of future royalties	(5,975)	(4,975)	(12,040)	(9,994)
Interest income and other income (expense), net	11,989	12,105	24,472	13,676
Total non-operating income (expense), net	783	1,745	1,975	(7,043)
Income (loss) before provision for income taxes	(110,187)	975,345	(229,682)	879,818
Provision (benefit) for income taxes	(278)	3,885	(1,261)	4,150
Net income (loss)	$ (109,909)	$ 971,460	$ (228,421)	$ 875,668
Net income (loss) per share:				
Basic	$ (0.63)	$ 5.67	$ (1.31)	$ 5.27
Diluted	$ (0.63)	$ 5.33	$ (1.31)	$ 4.91

Weighted average shares outstanding used in computing net income (loss) per share:

Basic	174,549	171,378	174,206	166,160
Diluted	174,549	182,291	174,206	178,281

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

	Six Months Ended June 30,	
	2019	2018
Cash flows from operating activities:		
Net income (loss)	$ (228,421)	$ 875,668
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Non-cash royalty revenue related to sale of future royalties	(17,321)	(15,965)
Non-cash interest expense on liability related to sale of future royalties	12,040	9,994
Stock-based compensation	49,907	40,608
Depreciation and amortization	6,132	5,115
Accretion of discounts, net and other non-cash transactions	(7,826)	(3,991)
Changes in operating assets and liabilities:		
Accounts receivable	5,914	(19,557)
Inventory	(1,807)	(1,158)
Other assets	15,818	(14,282)
Accounts payable	3,480	5,791
Accrued compensation	9,773	10,717
Other accrued expenses	15,508	15,417
Deferred revenue	(6,715)	(6,249)
Other liabilities	8,701	5,068
Net cash provided by (used in) operating activities	(134,817)	907,176
Cash flows from investing activities:		
Purchases of investments	(603,702)	(989,850)
Maturities of investments	634,145	132,779
Sales of investments	-	11,963
Purchases of property, plant and equipment	(17,291)	(3,730)
Sales of property, plant and equipment	-	2,633
Net cash provided by (used in) investing activities	13,152	(846,205)
Cash flows from financing activities:		
Issuance of common stock	-	790,231
Proceeds from shares issued under equity compensation plans	12,200	55,208
Net cash provided by financing activities	12,200	845,439
Effect of exchange rates on cash and cash equivalents	(16)	(47)
Net increase (decrease) in cash and cash equivalents	(109,481)	906,363
Cash and cash equivalents at beginning of period	194,905	4,762
Cash and cash equivalents at end of period	$ 85,424	$ 911,125
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 9,455	$ 9,795

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