

Nektar Therapeutics Reports Financial Results for the Second Quarter of 2018

August 8, 2018

SAN FRANCISCO, Aug. 8, 2018 /PRNewswire/ -- Nektar Therapeutics (Nasdaq: NKTR) today reported its financial results for the second quarter ended June 30, 2018.

Cash and investments in marketable securities at June 30, 2018 were \$2.1 billion as compared to \$353.2 million at December 31, 2017. This includes the \$1.0 billion upfront payment and \$850.0 million share purchase proceeds received on April 3, 2018, as a result of our Bristol-Myers Squibb collaboration for the global development and commercialization of NKTR-214.

"Over the past few months, we have reported significant progress across all areas of our pipeline, with notable milestones for our immuno-oncology, immunology and pain programs," said Howard W. Robin, President and CEO of Nektar. "Together with Bristol-Myers Squibb, we plan to initiate 20 registrational studies in nine tumor settings under our joint development plan with the first wave of studies in melanoma, renal cell carcinoma, and urothelial cancers starting this year. We initiated our first study of NKTR-358 in patients with lupus with our partner Eli Lilly. And importantly, we recently achieved a significant milestone for our pain program, with the FDA's acceptance of the NDA filing for NKTR-181, a first-in-class opioid analgesic."

Revenue in the second quarter of 2018 was \$1.088 billion as compared to \$34.6 million in the second quarter of 2017. Year-to-date revenue for 2018 was \$1.126 billion as compared to \$59.3 million in the first half of 2017. Revenue was higher in the second quarter and first half of 2018 as compared to the same periods in 2017 primarily because of the recognition of \$1.06 billion of license revenue from the Bristol-Myers Squibb collaboration agreement.

Total operating costs and expenses in the second quarter of 2018 were \$114.1 million as compared to \$85.2 million in the second quarter of 2017. Total operating costs and expenses in the first half of 2018 were \$238.9 million as compared to \$164.4 million in the first half 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 second quarter of 2018 was \$88.3 million as compared to \$60.3 million in the second quarter of 2017. For the first half of 2018, R&D expense was \$187.8 million as compared to \$121.3 million in the first half of 2017. R&D expense was higher in the second quarter and first half of 2018 as compared to the same periods in 2017 primarily because of expenses for our pipeline programs, including the continued development of NKTR-214 in Phase 1/2 studies and Phase 3 preparatory activities, costs related to the NKTR-181 New Drug Application and NKTR-181 pre-commercial manufacturing, Phase 1 clinical studies of 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 (G&A) expense was \$20.3 million in the second quarter of 2018 as compared to \$16.0 million in the second quarter of 2017. G&A expense in the first half of 2018 was \$38.9 million as compared to \$28.0 million in the first half of 2017. G&A expense was higher in the second quarter and first half of 2018 as compared to the same periods in 2017 primarily due to an increase in non-cash stock based compensation expense.

Net income in the second quarter of 2018 was \$971.5 million or \$5.33 diluted earnings per share as compared to a net loss of \$59.9 million or \$0.39 basic and diluted loss per share in the second quarter of 2017. Net income in the first half of 2018 was \$875.7 million or \$4.91 diluted earnings per share as compared to a net loss of \$123.7 million or \$0.80 basic and diluted loss per share in the first half of 2017.

Second Quarter 2018 and Recent Business Highlights

- In July, the U.S. Food and Drug Administration filed and accepted a New Drug Application (NDA) for NKTR-181, a first-in-class opioid analgesic, to treat chronic low back pain in adult patients new to opioid therapy. The NDA has been assigned a PDUFA (Prescription Drug User Fee Act) target action date of May 29, 2019 by the FDA.
- In June, Nektar presented data for NKTR-181 at the 80th Annual Scientific Meeting of the College on Problems of Drug Dependence. The data show that NKTR-181 consistently demonstrates low abuse potential.
- In June, Nektar presented data from the Phase 1 dose escalation and preliminary data from the Phase 2 dose expansion phase of the ongoing PIVOT study for NKTR-214 in combination with Opdivo (nivolumab) at the 2018 ASCO Annual Meeting. This data showed that pre-specified efficacy criteria were achieved in three tumor types: first-line melanoma, first-line renal cell carcinoma and first-line urothelial cancer. Nektar and Bristol-Myers Squibb expect to initiate a Phase 3 registrational trial in first-line advanced melanoma patients in Q3 2018, and pivotal studies are also being designed in renal cell carcinoma and urothelial cancer.
- In May, Nektar announced a clinical collaboration with Syndax Pharmaceuticals to evaluate NKTR-214 in combination with entinostat, an oral, small molecule Class 1 specific HDAC inhibitor, in patients with metastatic melanoma who have previously progressed on treatment with an anti-PD-1 agent.
- 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.

The company also announced the following upcoming presentations during the second half of 2018:

American Chemical Society Annual Meeting, Boston, MA:

- Oral Presentation: "Confronting the Opioid Epidemic: Novel Treatments for Chronic Pain"
 - o Presenter: Stephen Doberstein, Ph.D., Nektar Therapeutics
 - o Date: Monday, August, 20, 2018, 1:35 p.m. 2:05 p.m., Eastern Daylight Time

SMI Immuno-Oncology Conference, London, UK:

- Oral Presentation: "Enhanced cancer vaccine effectiveness with NKTR-214, a CD122-biased cytokine"
 - o Presenter: Loui Marakamutil, Ph.D., Nektar Therapeutics
 - o Date: September 26, 2018, 11:00 a.m., British Summer Time

Ninth American Conference on Pharmacometrics, San Diego, CA:

• Poster: "NKTR-255 Exhibits Target Mediated Drug Disposition and Stimulates Proliferation of Cytotoxic Immune Cells in Cyonomolgous Monkeys", Bhasi, K., et al.

o Date:October 6-12, 2018

ESMO 2018 Congress, Munich, Germany:

- Poster 362TiP: "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.
 - o Date: October 22, 2018, 12:45-13:45 p.m. Central European Summer Time
- Poster 446TiP: "REVEAL: A phase 1/2, open-label, multicenter, dose escalation and dose expansion study of NKTR-262 [TLR 7/8 agonist] plus NKTR-214 [CD122-biased agonist] with or without nivolumab (nivo) in patients (pts) with locally advanced or metastatic solid tumor malignancies.", Diab, A., et al.
 - o Date:October 22, 2018, 12:45-13:45 p.m. Central European Summer Time

Conference Call to Discuss Second 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 today, Wednesday, August 8, 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/. The web broadcast of the conference call will be available for replay through Monday, September 10, 2018.

To access the conference call, follow these instructions: Dial: (877) 881.2183 (U.S.); (970) 315.0453 (international) Passcode: 7099844 (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: "expect," "may," "will," "design," "develop," 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 initiation of Phase 3 registrational 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) 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 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-Q filed with the Securities and Exchange Commission on May 10, 2018. Any forward-lookin

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 Current assets:	June 30, 2018	December 31, 2017
Cash and cash equivalents	\$ 911,125	\$ 4,762
Short-term investments	912,683	291,370
Accounts receivable, net	35,315	5,014
Inventory	11,884	10,726
Other current assets	34,940	14,948
Total current assets	1,905,947	326,820
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Long-term investments	282,277	57,088
Property, plant and equipment, net	45,000	47,463
Goodwill	76,501	76,501
Other assets	3,362	994
Total assets	\$ 2,313,087	\$ 508,866
LIABILITIES AND STOCKHOLDERS' E Current liabilities:	QUITY	
Accounts payable	\$ 10,674	\$ 4,782
Accrued compensation	18,980	8,263
Accrued clinical trial expenses	20,028	9,461
Other accrued expenses	14,993	10,064
Interest payable	4,144	4,198
Deferred revenue, current portion	17,988	18,949
Other current liabilities	10,090	446
Total current liabilities	96,897	56,163
Senior secured notes, net	246,078	245,207
Liability related to the sale of future royalties, net	88,867	94,655
Deferred revenue, less current portion	13,780	19,021
Other long-term liabilities	7,051	5,992
Total liabilities	452,673	421,038
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	=	-
Common stock	17	15
Capital in excess of par value	3,094,095	2,207,865
Accumulated other comprehensive loss	(4,002)	(2,111)
Accumulated deficit	(1,229,696)	(2,117,941)
Total stockholders' equity	1,860,414	87,828
Total liabilities and stockholders' equity	\$ 2,313,087	\$ 508,866
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⁽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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Revenue:				
Product sales	\$ 5,863	\$ 15,693	\$ 12,158	\$ 20,449
Royalty revenue	8,563	7,434	19,639	14,651
Non-cash royalty revenue related to sale of future royalties	9,045	6,638	15,965	13,301
License, collaboration and other revenue	1,064,246	4,824	1,077,973	10,916
Total revenue	1,087,717	34,589	1,125,735	59,317
Operating costs and expenses:				
Cost of goods sold	5,522	8,989	12,168	15,120
Research and development	88,334	60,260	187,758	121,318
General and administrative	20,261	15,996	38,948	27,972
Total operating costs and expenses	114,117	85,245	238,874	164,410
Income (loss) from operations	973,600	(50,656)	886,861	(105,093)
Non-operating income (expense):				
Interest expense Non-cash interest expense on liability related to sale of future	(5,385)	(5,510)	(10,725)	(10,912)
royalties	(4,975)	(4,512)	(9,994)	(9,064)
Interest income and other income (expense), net	12,105	906	13,676	1,564
Total non-operating income (expense), net	1,745	(9,116)	(7,043)	(18,412)
Income (loss) before provision for income taxes	975,345	(59,772)	879,818	(123,505)
Provision for income taxes	3,885	99	4,150	232
Net income (loss)	\$ <u>971,460</u>	\$ (59,871)	\$ 875,668	\$ (123,737)
Net income (loss) per share:				
Basic	\$ 5.67	\$ (0.39)	\$ 5.27	\$ (0.80)
	\$ 5.33	\$ (0.39)	\$ 4.91	\$ (0.80)
Diluted	Ф 5.55	φ (0.39)	<u>\$ 4.91</u>	\$ (0.80)
Weighted average shares outstanding used in computing net income (loss) per share:				
Basic	171,378	155,352	166,160	154,514
Diluted	182,291	155,352	178,281	154,514

NEKTAR THERAPEUTICS CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands) (Unaudited)

	Six Months Ended June 30,		
	2018		2017
Cash flows from operating activities:			
Net income (loss)	\$	875,668	\$ (123,737)
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		(15,965)	(13,301)
Non-cash interest expense on liability related to sale of future royalties		9,994	9,064
Stock-based compensation		40,608	16,283
Depreciation and amortization		5,115	8,287
Other non-cash transactions		(3,991)	(1,089)
Changes in operating assets and liabilities:			
Accounts receivable, net		(19,557)	11,564
Inventory		(1,158)	101
Other assets		(14,282)	2,280
Accounts payable		5,791	3,221

Accrued compensation	10,717	(3,934)
Accrued clinical trial expenses	10,567	(1,275)
Other accrued expenses	4,904	2,388
Interest payable	(54)	(54)
Deferred revenue	(6,249)	(3,887)
Other liabilities	5,068_	1,000
Net cash provided by (used in) operating activities	907,176	(93,089)
Cash flows from investing activities:		
Purchases of investments	(989,850)	(121,135)
Maturities of investments	132,779	147,558
Sales of investments	11,963	8,823
Purchases of property, plant and equipment	(3,730)	(6,344)
Sales of property, plant and equipment	2,633	<u>-</u>
Net cash (used in) provided by investing activities	(846,205)	28,902
Cash flows from financing activities:		
Payment of capital lease obligations	-	(1,369)
Issuance of common stock	790,231	-
Proceeds from shares issued under equity compensation plans	55,208	22,016
Net cash provided by financing activities	845,439	20,647
Effect of exchange rates on cash and cash equivalents	(47)	49
Net increase (decrease) in cash and cash equivalents	906,363	(43,491)
Cash and cash equivalents at beginning of period	4,762	59,640
Cash and cash equivalents at end of period	\$ 911,125	\$ 16,149
Supplemental disclosure of cash flow information:		
••	\$ 9,795	\$ 10,010
Cash paid for interest	ψ 9,195	Ψ 10,010

C View original content: http://www.prnewswire.com/news-releases/nektar-therapeutics-reports-financial-results-for-the-second-quarter-of-2018-300694282.html

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