



Nektar Therapeutics Reports Financial Results for the Third Quarter of 2019

November 6, 2019

SAN FRANCISCO, Nov. 6, 2019 /PRNewswire/ -- Nektar Therapeutics (Nasdaq: NKTR) today reported its financial results for the third quarter ended September 30, 2019.

Cash and investments in marketable securities at September 30, 2019 were approximately \$1.7 billion as compared to \$1.9 billion at December 31, 2018.

"We continue to make steady progress with our diverse portfolio of immuno-oncology and immunology programs," said Howard W. Robin, President and CEO of Nektar. "With our partner Bristol-Myers Squibb, we are conducting registrational trials evaluating the combination of bempegaldesleukin with nivolumab in melanoma, urothelial cancer and renal cell carcinoma. We are also working collaboratively with BMS to finalize the next set of registrational studies. This weekend at the SITC Annual Meeting, we are excited to present an 18-month follow-up for patients with metastatic melanoma enrolled in our PIVOT-02 study. This follows the recent announcement of our Breakthrough Therapy Designation for the doublet which was granted by FDA in August for patients with previously untreated metastatic melanoma. For NKTR-358, we now have three separate Phase 1b clinical trials ongoing in lupus, psoriasis and atopic dermatitis with our partner Eli Lilly, with plans to add an additional autoimmune indication to the development program in 2020. And importantly, we initiated our first clinical trial for NKTR-255, our novel IL-15 agonist, in patients with non-Hodgkin lymphoma and multiple myeloma."

Revenue in the third quarter of 2019 was \$29.2 million as compared to \$27.8 million in the third quarter of 2018. Year-to-date revenue for 2019 was \$80.8 million as compared to \$1.15 billion in the first nine months of 2018. Revenue was higher in the third quarter of 2019 as compared to the same period in 2018 primarily due to non-cash royalty revenue and an increase in product sales. Revenue was lower in the first nine months of 2019 as compared to the same period 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 third quarter of 2019 were \$128.0 million as compared to \$126.4 million in the third quarter of 2018. Total operating costs and expenses in the first nine months of 2019 were \$411.2 million as compared to \$365.3 million in the same period of 2018. Total operating costs and expenses increased marginally in the third quarter of 2019 as compared to the third quarter of 2018 due to a decrease in research and development (R&D) expense, offset by an increase in general and administrative (G&A) expense. Total operating costs and expenses increased in the first nine months of 2019 as compared to the same period in 2018 due to increases in both R&D and G&A expense.

R&D expense in the third quarter of 2019 was \$99.0 million as compared to \$102.9 million for the third quarter of 2018. For the first nine months of 2019, R&D expense was \$324.2 million as compared to \$290.7 million in the first nine months of 2018. R&D expense was lower in the third quarter of 2019 as compared to the same period in 2018 due to decreased expense for the bempegaldesleukin program. R&D expense was higher in the first nine months 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.

G&A expense was \$24.0 million in the third quarter of 2019 as compared to \$18.7 million in the third quarter of 2018. G&A expense in the first nine months of 2019 was \$71.6 million as compared to \$57.7 million in the first nine months of 2018. G&A expense was higher in the third quarter and first nine months of 2019 as compared to the same periods in 2018 due to costs related to commercialization readiness activities for NKTR-181 and bempegaldesleukin, and increased non-cash stock-based compensation.

Net loss in the third quarter of 2019 was \$98.8 million or \$0.56 basic and diluted loss per share as compared to net loss of \$96.1 million or \$0.56 basic and diluted loss per share in the third quarter of 2018. Net loss in the first nine months of 2019 was \$327.2 million or \$1.87 basic and diluted loss per share as compared to net income of \$779.5 million or \$4.34 diluted income per share in the first nine months of 2018.

Third Quarter 2019 and Recent Business Highlights

- In September, Nektar presented clinical data from its PIVOT-02 study for bempegaldesleukin in combination with Opdivo (nivolumab) at the 2019 CRI-CIMT-EATI-AACR International Cancer Immunotherapy Conference demonstrating the promising clinical activity of the combination in patients with advanced or metastatic triple-negative breast cancer, particularly in patients with PD-L1 negative baseline tumors.
- In October, Nektar announced that its partner Eli Lilly initiated two Phase 1b studies of NKTR-358, a novel T regulatory (Treg) cell stimulator, one in patients with psoriasis and one in patients with atopic dermatitis. NKTR-358 is designed to treat autoimmune and inflammatory conditions by correcting the immune system imbalance that results from reduced numbers and impaired function of immune regulating Treg cells.
- In October, Nektar announced the initiation of a first-in-human, Phase 1 clinical study evaluating NKTR-255, an interleukin-15 (IL-15) receptor agonist, as monotherapy for patients with relapsed or refractory non-Hodgkin lymphoma or multiple myeloma (MM). The study will also combine NKTR-255 with multiple targeted antibodies that function through an antibody-dependent cell-mediated cytotoxicity mechanism to evaluate the safety and efficacy in adults with relapsed or refractory MM.

The company also announced upcoming presentations at the following scientific congresses:

2019 Society for Immunotherapy and Cancer (SITC) Annual Meeting, National Harbor, MD:

- **Oral Presentation:** *"Clinical activity of BEMPEG plus NIVO in previously untreated patients with metastatic melanoma: updated results from the phase 1/2 PIVOT-02 study"*
 - **Presenter:** Dr. Adi Diab, MD Anderson Cancer Center
 - **Session:** Concurrent Session 310: Combination Phase 1-2 Clinical Trials
 - **Date:** Saturday, November 9, 2019, 5:15 p.m. – 5:30 p.m. Eastern Standard Time

- **Poster:** *"NKTR-255, a polymer-conjugated IL-15 receptor agonist, enhances efficacy of therapeutic monoclonal antibodies with ADCC activity in solid tumor models", Kivimäe, S., et al.*
 - **Session Date and Time:** Friday, November 8, 2019, 7:00 a.m. - 8:00 p.m. Eastern Standard Time

- **Poster:** *"Bempegaldesleukin in combination with local radiation and systemic checkpoint blockade induces a robust systemic anti-tumor immunity", Pieper, A., et al.*
 - **Session Date and Time:** Friday, November 8, 2019, 7:00 a.m. - 8:00 p.m. Eastern Standard Time

- **Poster:** *"Characterization and comparison of NKTR-255, a polymer-conjugated IL-15 versus IL-15 superagonist", Miyazaki, T., et al.*
 - **Session Date and Time:** Saturday, November 9, 2019, 7:00 a.m. - 8:00 p.m. Eastern Standard Time

- **Trials in Progress Poster:** *"A multicenter, open-label, exploratory platform study to evaluate biomarkers and immunotherapy combinations for the treatment of patients with metastatic castration-resistant prostate cancer (PORTER)", Nissola, L., et al.*
 - **Session Date and Time:** Friday, November 8, 2019, 7:00 a.m. - 8:00 p.m. Eastern Standard Time

ACR 2019 American College of Rheumatology Annual Meeting, Atlanta, GA:

- **Poster:** *"Selective induction of functional regulatory T-cells in healthy volunteers by NKTR-358, a novel IL-2 conjugate Treg stimulator, in development for the treatment of autoimmune diseases", Fanton, C., et al.*
 - **Session:** T Cell Biology & Targets in Autoimmune & Inflammatory Disease Poster
 - **Date:** Sunday, November 10, 2019, 9:00 a.m. – 11:00 a.m. Eastern Standard Time

The Promise of Interleukin-2 Therapy 2019, Paris, France:

- **Presentation:** *"NKTR-358: A polymer-conjugated IL-2 that drives the selective expansion of endogenous Tregs for the treatment of autoimmune diseases"*
 - **Presenter:** Christine Fanton, Ph.D., Nektar Therapeutics
 - **Session:** Session V.a – Novel IL-2s
 - **Date:** Friday, November 15, 2019, 2:00 p.m. Central European Time

- **Presentation:** *"Bempegaldesleukin: A polymer-conjugated IL-2 prodrug for multiple immune oncology applications"*
 - **Presenter:** Loui Madakamutil, Ph.D., Nektar Therapeutics
 - **Session:** Session VI – IL-2 in cancer therapy
 - **Date:** Friday, November 15, 2019, 4:30 p.m. Central European Time

11th Annual PEGs Europe, Lisbon, Portugal:

- **Presentation:** *"TLR Agonist NKTR-262 Immunotherapy Combination with Bempegaldesleukin (NKTR-214) Harnessing Innate and Adaptive Immune System for the Treatment of Solid Tumors"*
 - **Presenter:** Saul Kivimäe, Ph.D., Nektar Therapeutics
 - **Session:** Reprogramming the Microenvironment/The Innate Immune System/Glyco-immune Checkpoints
 - **Date:** Tuesday, November 19, 2019, 5:30 p.m. Western European Time

- **Presentation:** *"NKTR-255: A Polymer-Conjugated IL-15 that Enhances CAR T Efficacy in Murine Models"*
 - **Presenter:** Loui Madakamutil, Ph.D., Nektar Therapeutics
 - **Session:** TILs and Gamma Delta Therapy
 - **Date:** Thursday, November 21, 2019, 11:15 a.m. Western European Time

Melanoma Bridge 2019, Naples, Italy:

- **Presentation:** *"Clinical activity of BEMPEG plus NIVO in previously untreated patients with metastatic melanoma: updated*

results from the phase 1/2 PIVOT-02 study"- [Encore Presentation]

- o **Presenter:** Igor Puzanov, M.D., Roswell Park Comprehensive Cancer Center, Melanoma Bridge Co-chair
- o **Session:** Emergent Strategies Session
- o **Date:** Saturday, December 7, 2019, 12:00 p.m. – 12:15 p.m. Central European Time

61st American Society of Hematology (ASH) Annual Meeting & Exposition, Orlando, FL:

- **Poster:** "Combination of NKTR-255, a Polymer Conjugated Human IL-15, with CD19 CAR T Cell Immunotherapy in a Preclinical Lymphoma Model", Chou, C., et al.
 - o **Session:** 625. Lymphoma: Pre-Clinical—Chemotherapy and Biologic Agents: Poster II
 - o **Date:** Sunday, December 8, 2019, 6:00 p.m. - 8:00 p.m. Eastern Standard Time
- **Poster:** "Restoring Innate and Adaptive Immune Repertoire in Multiple Myeloma for Therapeutic Application", Fernandez, R., et al.
 - o **Session:** 652. Myeloma: Pathophysiology and Pre-Clinical Studies, Excluding Therapy: Poster III
 - o **Date:** Monday, December 9, 2019, 6:00 p.m. - 8:00 p.m. Eastern Standard Time
- **Trials in Progress Poster:** "A Phase 1, Open-Label, Multi-Center, Dose Escalation and Dose Expansion Study of NKTR-255 As a Single Agent in Relapsed or Refractory Hematologic Malignancies and in Combination with Daratumumab As a Salvage Regimen for Multiple Myeloma", Shah, N. et al.
 - o **Session:** 704. Immunotherapies: Poster III
 - o **Date:** Monday, December 9, 2019; 6:00 p.m. - 8:00 p.m. Eastern Standard 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 Standard Time/2:00 p.m. Pacific Standard Time, Wednesday, November 6, 2019.

This press release and a 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, December 9, 2019.

To access the conference call, follow these instructions:

Dial: (877) 881-2183 (U.S.); (970) 315-0453 (international)
Conference ID: 3079832 (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 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," "plan," "finalizing," "design," "evaluate," "promise," "potential," "continue," "may," "will" and similar references to future periods. Examples of forward-looking statements include, among others, statements we make regarding the finalization of a joint development plan to study bempegaldesleukin ("bempeg"), the potential therapeutic benefits of our investigational products (including bempeg, NKTR-358 and NKTR-255) and future plans to clinically study our investigational products in one or more particular indications, 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, delays caused by our collaboration partners, and enrollment competition; (ii) 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 bempeg, NKTR-358, and NKTR-255) is therefore highly uncertain and unpredictable and one or more of these programs may fail; (iii) 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 (iv) 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 August 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	<u>September 30, 2019</u>	<u>December 31, 2018</u> ⁽¹⁾
Current assets:		
Cash and cash equivalents	\$ 81,224	\$ 194,905
Short-term investments	1,414,448	1,140,445
Accounts receivable	41,205	43,213
Inventory	13,720	11,381
Advance payments to contract manufacturers	13,015	26,450
Other current assets	<u>15,212</u>	<u>21,293</u>
Total current assets	1,578,824	1,437,687
Long-term investments	231,082	582,889
Property, plant and equipment, net	64,614	48,851
Operating lease right-of-use assets	134,888	-
Goodwill	76,501	76,501
Other assets	<u>2,385</u>	<u>4,244</u>
Total assets	<u>\$ 2,088,294</u>	<u>\$ 2,150,172</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 21,963	\$ 5,854
Accrued compensation	23,101	9,937
Accrued clinical trial expenses	38,338	14,700
Accrued contract manufacturing expenses	8,646	23,841
Other accrued expenses	11,394	9,580
Interest payable	4,198	4,198
Operating lease liabilities, current portion	9,318	-
Deferred revenue, current portion	<u>8,392</u>	<u>13,892</u>
Total current liabilities	125,350	82,002
Senior secured notes, net	248,257	246,950
Operating lease liabilities, less current portion	145,099	-
Liability related to the sale of future royalties, net	73,455	82,911
Deferred revenue, less current portion	6,779	10,744
Other long-term liabilities	<u>643</u>	<u>9,990</u>
Total liabilities	599,583	432,597
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	-	-
Common stock	17	17
Capital in excess of par value	3,241,160	3,147,925
Accumulated other comprehensive loss	(1,186)	(6,316)
Accumulated deficit	<u>(1,751,280)</u>	<u>(1,424,051)</u>
Total stockholders' equity	1,488,711	1,717,575
Total liabilities and stockholders' equity	<u>\$ 2,088,294</u>	<u>\$ 2,150,172</u>

(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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenue:				
Product sales	\$ 5,558	\$ 4,256	\$ 14,302	\$ 16,414
Royalty revenue	10,275	10,259	29,008	29,898
Non-cash royalty revenue related to sale of future royalties	10,264	8,372	27,585	24,337
License, collaboration and other revenue	3,121	4,875	9,860	1,082,848
Total revenue	29,218	27,762	80,755	1,153,497
Operating costs and expenses:				
Cost of goods sold	4,927	4,783	15,385	16,951
Research and development	99,048	102,895	324,197	290,653
General and administrative	23,983	18,718	71,570	57,666
Total operating costs and expenses	127,958	126,396	411,152	365,270
Income (loss) from operations	(98,740)	(98,634)	(330,397)	788,227
Non-operating income (expense):				
Interest expense	(5,425)	(5,442)	(15,882)	(16,167)
Non-cash interest expense on liability related to sale of future royalties	(5,813)	(4,814)	(17,853)	(14,808)
Interest income and other income (expense), net	11,492	11,847	35,964	25,523
Total non-operating income (expense), net	254	1,591	2,229	(5,452)
Income (loss) before provision for income taxes	(98,486)	(97,043)	(328,168)	782,775
Provision (benefit) for income taxes	322	(900)	(939)	3,250
Net income (loss)	\$ (98,808)	\$ (96,143)	\$ (327,229)	\$ 779,525
Net income (loss) per share:				
Basic	\$ (0.56)	\$ (0.56)	\$ (1.87)	\$ 4.63
Diluted	\$ (0.56)	\$ (0.56)	\$ (1.87)	\$ 4.34
Weighted average shares outstanding used in computing net income (loss) per share:				
Basic	175,402	172,698	174,609	168,363
Diluted	175,402	172,698	174,609	179,619

NEKTAR THERAPEUTICS
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2019	2018
Cash flows from operating activities:		
Net income (loss)	\$ (327,229)	\$ 779,525
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	(27,585)	(24,337)
Non-cash interest expense on liability related to sale of future royalties	17,853	14,808
Stock-based compensation	74,787	63,895
Depreciation and amortization	9,582	7,799
Accretion of discounts, net and other non-cash transactions	(10,421)	(8,136)
Changes in operating assets and liabilities:		
Accounts receivable	2,008	(16,179)
Inventory	(2,339)	(2,570)
Other assets	18,127	(22,087)
Accounts payable	16,109	2,611
Accrued compensation	13,164	19,659
Other accrued expenses	10,019	26,603
Deferred revenue	(9,465)	(10,931)
Other liabilities	11,932	5,104
Net cash provided by (used in) operating activities	(203,458)	835,764
Cash flows from investing activities:		
Purchases of investments	(1,028,883)	(1,944,178)

Maturities of investments	1,122,902	467,658
Sales of investments	-	11,963
Purchases of property, plant and equipment	(22,614)	(5,552)
Sales of property, plant and equipment	-	2,633
Net cash provided by (used in) investing activities	71,405	(1,467,476)
Cash flows from financing activities:		
Issuance of common stock	-	790,231
Proceeds from shares issued under equity compensation plans	18,449	59,067
Net cash provided by financing activities	18,449	849,298
Effect of exchange rates on cash and cash equivalents	(77)	(87)
Net increase (decrease) in cash and cash equivalents	(113,681)	217,499
Cash and cash equivalents at beginning of period	194,905	4,762
Cash and cash equivalents at end of period	<u>\$ 81,224</u>	<u>\$ 222,261</u>
Supplemental disclosure of cash flow information:		
Cash paid for interest	<u>\$ 14,229</u>	<u>\$ 14,701</u>

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