Nektar Therapeutics Reports Third Quarter 2020 Financial Results

November 5, 2020

SAN FRANCISCO, Nov. 5, 2020 /PRNewswire/ -- Nektar Therapeutics (NASDAQ: NKTR) today reported financial results for the third quarter ended September 30, 2020.

Cash and investments in marketable securities at September 30, 2020 were approximately $1.2 billion as compared to $1.6 billion at December 31, 2019.

"In Q3, we've continued to successfully advance our late-stage registrational and early stage studies for our immune-oncology pipeline of candidates while navigating challenges in the current COVID-19 environment," said Howard W. Robin, President and CEO of Nektar. "Enrollment in our five registrational trials of bempegaldesleukin in combination with nivolumab is going well and our partner BMS recently initiated a new clinical study in renal cell carcinoma to evaluate the doublet therapy with a TKI agent. We are also pleased to report that we are ahead of our enrollment targets for the Phase 2 PROPEL study of bempegaldesleukin with pembrolizumab in patients with metastatic non-small cell lung cancer and we look forward to sharing the initial data from this important study in the first part of 2021."

"Next week's 2020 SITC meeting will feature data presentations that showcase the strength of Nektar's immune-oncology pipeline, including an oral presentation of 2 1/2 year data for metastatic melanoma patients treated with bempegaldesleukin plus nivolumab, and promising early data for NKTR-255, our IL-15 cytokine, as well as NKTR-262, our TLR agonist program," continued Robin. "In immunology, we presented positive new data at ACR 2020 this week highlighting the disease activity observed in lupus patients with NKTR-358, our T regulatory cell agent. We are exceptionally pleased that our partner Lilly is undertaking a broad clinical development program for NKTR-358 with two Phase 1b studies in atopic dermatitis and psoriasis, a Phase 2 study underway in patients with systemic lupus erythematosus and a new Phase 2 study being planned in ulcerative colitis."

Summary of Q3 2020 Financial Results

Revenue in the third quarter of 2020 was $30.0 million compared to $29.2 million in the third quarter of 2019. Year-to-date revenue for 2020 was $129.5 million compared to $80.8 million for the first nine months of 2019. Revenue was higher due to the recognition of $50.0 million in total milestones from Bristol-Myers Squibb related to the start of two new registrational trials of bempegaldesleukin plus Opdivo® in adjuvant melanoma and muscle-invasive bladder cancer.

Total operating costs and expenses in the third quarter of 2020 were $133.1 million compared to $128.0 million in the third quarter of 2019. Total operating costs and expenses in the first nine months of 2020 were $443.8 million compared to $411.2 million in the first nine months of 2019. Year-to-date operating costs and expenses increased primarily as a result of $45.2 million in impairment charges in the first quarter of 2020 resulting from the discontinuation of the NKTR-181 program, partially offset by a decrease in R&D expense.

R&D expense in the third quarter of 2020 was $100.5 million compared to $99.0 million for the third quarter of 2019. For the first nine months of 2020, R&D expense was $306.0 million compared to $324.2 million in the first nine months of 2019. Excluding pre-commercial manufacturing costs for NKTR-181 incurred during 2019, research and development expense increased for the third quarter and the first nine months of 2020 primarily due to increases in clinical development costs, partially offset by a decrease in manufacturing costs for clinical trial materials.

Net loss for the third quarter of 2020 was $108.6 million or $0.61 basic and diluted loss per share compared to a net loss of $98.6 million or $0.56 basic and diluted loss per share in the third quarter of 2019. Net loss in the first nine months of 2020 was $327.2 million or $1.84 basic and diluted loss per share compared to a net loss of $328.5 million or $1.88 basic and diluted loss per share in the first nine months of 2019.

Third Quarter 2020 and Recent Business Highlights

- In November 2020, Nektar presented new data from its NKTR-358 program at the American College of Rheumatology (ACR) virtual meeting. Data from the Phase 1b study in patients with mild to moderate systemic lupus erythematosus (SLE) showed that NKTR-358 produced a dose-dependent increase in expression of Treg activation markers, providing a rationale for continued development in SLE and other inflammatory indications.
- In October 2020, Nektar received IND clearance and began site initiation activities for a Phase 1/2 study of NKTR-255 in patients with solid tumors. The study will evaluate NKTR-255 in combination with cetuximab in two distinct groups of highly refractory patients with colorectal cancer or head and neck cancer.
- In October 2020, Nektar initiated a Phase 1b clinical study of bempegaldesleukin in adult patients with mild COVID-19 infection. The randomized, double-blind, placebo-controlled trial is designed to assess the safety, tolerability, and pharmacokinetic and pharmacodynamic profile of bempegaldesleukin in adult patients with mild COVD-19.
- In September 2020, a Phase 1/2 study was initiated by Nektar partner BMS in patients with clear cell renal cell carcinoma to evaluate the triplet combination of bempegaldesleukin with nivolumab in combination with a tyrosine-kinase inhibitor.
- In August 2020, Vaccibody AS and Nektar announced that the first patient had been dosed in the Phase 1/2a study evaluating bempegaldesleukin with VB10.NEO, Vaccibody's personalized neoantigen cancer vaccine, in patients with advanced squamous cell carcinoma of the head and neck.

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

2020 Society for Immunotherapy of Cancer (SITC) Annual Meeting:

- **Oral Presentation:** *"REVEAL: Phase 1 dose-escalation study of NKTR-262, a novel TLR7/8 agonist, plus bempegaldesleukin: local innate immune activation and systemic adaptive immune expansion for treating solid tumors"*
  - **Presenter:** Dr. Adi Diab, MD Anderson Cancer Center
  - **Session:** Session 102: Combinatorial Therapies
  - **Date and Time:** Wednesday, November 11; 11:15 a.m. – 1:10 p.m. Eastern Standard Time
- **Oral Presentation:** *"Progression-free survival and biomarker correlates of response with BEMPEG plus NIVO in previously untreated patients with metastatic melanoma: results from the PIVOT-02 study"*
  - **Presenter:** Dr. Adi Diab, MD Anderson Cancer Center
  - **Session:** Session 104: Concurrent Rapid Oral Abstract Presentation: Clinical
  - **Date and Time:** Wednesday, November 11; 1:30 p.m. – 2:00 p.m. Eastern Standard Time
- **Poster Presentation:** *"First-in-human phase I study of NKTR-255 in patients with relapsed/refractory hematologic malignancies"*, Shah, N., et al.
  - **Session:** Virtual Poster Hall
  - **Date and Time:** Poster presentations will be available beginning November 9, 2020
- **Poster Presentation:** "*Bempegaldesleukin (BEMPEG; CD122-preferential IL-2 pathway agonist)) and NKTR-262 (TLR7/8 agonist) combination treatment pairs local innate immune activation with systemic CD8+ T cell expansion to enhance anti-tumor immunity*", Rolig, A., et al.
  - **Session:** Virtual Poster Hall
  - **Date and Time:** Poster presentations will be available beginning November 9, 2020

Conference Call to Discuss Third Quarter 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, November 5, 2020.

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 Tuesday, December 1, 2020.

To access the conference call, follow these instructions:

Dial: (877) 881-2183 (U.S.); (970) 315-0453 (international)
Conference ID: 5192707 (Nektar Therapeutics is the host)

About Nektar Therapeutics

Nektar Therapeutics is a biopharmaceutical company with a robust, wholly owned R&D pipeline of investigational medicines in oncology, immunology, and virology, as well as a portfolio of approved partnered medicines. 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 forward-looking statements which can be identified by words such as: "may," "design," "potential," "evaluate," "plan," "will," and similar references to future periods. Examples of forward-looking statements include, among others, statements we make regarding the therapeutic potential of, and future development plans for, our clinical drug candidates, and the timing of the initiation of clinical studies for our clinical drug candidates. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they 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. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results to differ materially from those indicated in the forward-looking statements include, among others: (i) our statements regarding the therapeutic potential of bempegaldesleukin in patients who have been diagnosed with COVID-19 infection are based on data that is evolving and do not include clinical testing of bempegaldesleukin for this intended patient population, and there is no guarantee that the clinical evaluation of bempegaldesleukin in COVID-19 patients will support the use of bempegaldesleukin in this patient population; (ii) investigational agents and continued research and development for these drug candidates are subject to substantial risks, including negative safety and efficacy findings in ongoing clinical studies (notwithstanding positive findings in earlier preclinical and clinical studies); (iii) as our clinical drug candidates are currently in development, the risk of failure is high and failure can unexpectedly occur at any stage prior to regulatory approval; (iv) the timing of the commencement or end of clinical trials 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, competitive factors, or delay or failure in ultimately obtaining regulatory approval in one or more important markets; (v) 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 (vi) certain other important risks and uncertainties set forth in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 7, 2020. 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, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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

ASSETS	September 30, 2020	December 31, 2019 (1)
Current assets:		
Cash and cash equivalents	$ 55,843	$ 96,363
Short-term investments	900,163	1,228,499
Accounts receivable	42,925	36,802
Inventory	12,892	12,665
Advance payments to contract manufacturers	10,483	31,834
Other current assets	21,550	15,387
Total current assets	1,043,856	1,421,550
Long-term investments	197,715	279,119
Property, plant and equipment, net	60,189	65,665
Operating lease right-of-use assets	128,985	134,177
Goodwill	76,501	76,501
Other assets	1,420	344
Total assets	$ 1,508,666	$ 1,977,356
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Senior secured notes, net and interest payable	$ -	$ 252,891
Accounts payable	15,484	19,234
Accrued compensation	29,504	11,467
Accrued clinical trial expenses	48,886	32,626
Accrued contract manufacturing expenses	7,141	7,304
Other accrued expenses	9,630	12,338
Operating lease liabilities, current portion	15,348	12,516
Deferred revenue, current portion	507	5,517
Total current liabilities	126,500	353,893
Operating lease liabilities, less current portion	139,022	142,730
Liability related to the sale of future royalties, net	66,378	72,020
Deferred revenue, less current portion	2,494	2,554
Other long-term liabilities	3,291	768
Total liabilities	337,685	571,965
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	-	-
Common stock	18	17
Capital in excess of par value	3,363,998	3,271,097
Accumulated other comprehensive income (loss)	(1,080)	(1,005)
Accumulated deficit	(2,191,955)	(1,864,718)
Total stockholders' equity	1,170,981	1,405,391
Total liabilities and stockholders' equity	$ 1,508,666	$ 1,977,356

(1) The consolidated balance sheet at December 31, 2019 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,	
	2020	2019	2020	2019
Revenue:				
Product sales	$ 5,691	$ 5,558	$ 14,620	$ 14,302
Royalty revenue	12,289	10,275	31,411	29,008
Non-cash royalty revenue related to sale of future royalties	10,422	10,264	28,001	27,585
License, collaboration and other revenue	1,631	3,121	55,421	9,860
Total revenue	30,033	29,218	129,453	80,755
Operating costs and expenses:				
Cost of goods sold	5,570	4,927	15,154	15,385
Research and development	100,531	99,048	305,954	324,197
General and administrative	26,982	23,983	77,546	71,570
Impairment of assets and other costs for terminated program	-	-	45,189	-
Total operating costs and expenses	133,083	127,958	443,843	411,152
Loss from operations	(103,050)	(98,740)	(314,390)	(330,397)
Non-operating income (expense):				
Interest expense	-	(5,425)	(6,851)	(15,882)
Non-cash interest expense on liability related to sale of future royalties	(8,425)	(5,813)	(22,084)	(17,853)
Interest income and other income (expense), net	2,910	11,492	16,453	35,964
Total non-operating income (expense), net	(5,515)	254	(12,482)	2,229
Loss before provision for income taxes	(108,565)	(98,486)	(326,872)	(328,168)
Provision for income taxes	21	99	365	335
Net loss	$ (108,586)	$ (98,585)	$ (327,237)	$ (328,503)
Basic and diluted net loss per share	$ (0.61)	$ (0.56)	$ (1.84)	$ (1.88)
Weighted average shares outstanding used in computing basic and diluted net loss per share	179,090	175,402	178,203	174,609

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

	Nine Months Ended September 30,	
	2020	2019
Cash flows from operating activities:		
Net loss	$ (327,237)	$ (328,503)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash royalty revenue related to sale of future royalties	(28,001)	(27,585)
Non-cash interest expense on liability related to sale of future royalties	22,084	17,853
Stock-based compensation	72,274	74,787
Depreciation and amortization	10,937	9,582
Impairment of advance payments to contract manufacturers and equipment for terminated program	20,351	-
Accretion of premiums (discounts), net and other non-cash transactions	1,150	(9,147)
Changes in operating assets and liabilities:		
Accounts receivable	(6,123)	2,008

Inventory	(227)	(2,339)
Operating leases, net	4,316	11,550
Other assets	(5,588)	18,127
Accounts payable	(3,337)	16,109
Accrued compensation	20,478	13,164
Other accrued expenses	9,340	10,401
Deferred revenue	(5,070)	(9,465)
Net cash used in operating activities	(214,653)	(203,458)
Cash flows from investing activities:		
Purchases of investments	(791,445)	(1,028,883)
Maturities of investments	1,158,722	1,122,902
Sales of investments	41,700	-
Purchases of property, plant and equipment	(5,504)	(22,614)
Net cash provided by investing activities	403,473	71,405
Cash flows from financing activities:		
Proceeds from shares issued under equity compensation plans	20,651	18,449
Repayment of Senior Notes	(250,000)	-
Net cash provided by (used in) financing activities	(229,349)	18,449
Effect of exchange rates on cash and cash equivalents	9	(77)
Net decrease in cash and cash equivalents	(40,520)	(113,681)
Cash and cash equivalents at beginning of period	96,363	194,905
Cash and cash equivalents at end of period	$ 55,843	$ 81,224
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 9,742	$ 14,299
Operating lease right-of-use asset recognized in exchange for lease liabilities	$ 2,133	$ 56,025

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