

May 14, 2018



# BioXcel Therapeutics Reports First Quarter 2018 Financial Results and Provides Business Update

BRANFORD, Conn., May 14, 2018 (GLOBE NEWSWIRE) -- BioXcel Therapeutics, Inc. ("BTI") (Nasdaq:BTAI), a clinical stage biopharmaceutical development company utilizing novel artificial intelligence to identify the next wave of medicines across neuroscience and immuno-oncology, today announced financial results for the first quarter ended March 31, 2018, and provided an update on key strategic and operational initiatives.

"The first quarter of 2018 was a transformational period for our company. We successfully completed our initial public offering (IPO), strengthening our balance sheet and providing capital to advance our drug candidates through clinical trials. We are grateful for the support of our investors as we advance our lead programs, BXCL501 in neuroscience and BXCL701 in immuno-oncology," commented Vimal Mehta, President and Chief Executive Officer of BTI.

"Building on this momentum, we are continuing to advance our BXCL501 program through the ongoing trial of the IV formulation of dexmedetomidine ("Dex") and plan to initiate a second IV Dex study for the acute treatment of agitation in schizophrenic patients. We expect to report data from both Phase 1b studies in the second half of 2018. Following data, we intend to commence Phase 2 Proof-of-Concept open label clinical trials using the IV formulation of Dex for both programs before year-end, and a bridging bioavailability / bioequivalence study using our sublingual thin film formulation of Dex, BXCL501, which we expect will support initiation of a registration trial anticipated in 2019.

Dr. Mehta added, "We are also making significant progress in the development of BXCL701, our oral small molecule immunomodulator. We are planning to initiate Phase 2 proof of concept studies in pancreatic cancer and treatment-emergent neuroendocrine prostate cancer (tNEPC) later this year. We are also evaluating BXCL701's potential in additional indications, both as a monotherapy and in combination with other immuno-oncology agents. We believe that its novel mechanism of action, DPP 8/9 and FAP inhibition, makes it a promising therapy in the treatment of a variety of tumor types."

Dr. Mehta concluded, "We have an exciting opportunity ahead of us through our relationship with BioXcel Corporation. Its artificial intelligence-based discovery platform is expected to be an invaluable tool as we advance our clinical programs and identify emerging pipeline candidates. Through this relationship, we expect to have the ability to leverage thousands of compounds and disease targets to expand our pipeline with the addition of innovative treatment regimens that we can develop quickly, at a lower cost, and with a high probability of success. Since completion of our IPO, we have been building our corporate operations team and expanding scientific, clinical, manufacturing, quality, regulatory and R&D staff to support our future growth and the advancement of both our clinical and pipeline programs."

## First Quarter 2018 Highlights

- Completed IPO and began trading on Nasdaq Capital Market, raising gross proceeds of \$60.0 million;
- Announced acceptance of poster presentation on preclinical data for combination of BXCL701 and Nektar Therapeutics' NKTR-214 in pancreatic cancer at the 2018 ASCO Annual Meeting.

## First Quarter 2018 Financial Results

BTI reported a net loss of \$4.3 million for the first quarter of 2018, compared to a net loss of \$0.5 million for the same period in 2017.

Research and development expenses were \$2.9 million for the first quarter of 2018, as compared to \$0.3 million for the same period in 2017. The increase was primarily due to a ramp-up of research and development costs including a one-time previously agreed \$1.0 million payment to BioXcel Corporation in connection with BTI's IPO, along with increased personnel expenses associated with BTI's two main drug candidates.

General and administrative expenses were \$1.3 million for the first quarter of 2018, as compared to \$0.2 million for the same period in 2017. The increase was primarily due to additional payroll and payroll-related expenses and costs associated with operating as a public company.

As of March 31, 2018, cash and cash equivalents totaled \$55.5 million.

#### **About BioXcel Therapeutics, Inc.:**

BioXcel Therapeutics, Inc. is a clinical stage biopharmaceutical company focused on drug development that utilizes novel artificial intelligence to identify the next wave of medicines across neuroscience and immuno-oncology. The Company's drug re-innovation approach leverages existing approved drugs and/or clinically validated product candidates together with big data and proprietary machine learning algorithms to identify new therapeutic indices. The Company's two most advanced clinical development programs are BXCL501, a sublingual thin film formulation designed for acute treatment of agitation resulting from neurological and psychiatric disorders, and BXCL701, an immuno-oncology agent designed for treatment of a rare form of prostate cancer and for treatment of pancreatic cancer.

#### **Forward-Looking Statements:**

*This press release includes "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this press release include, but are not limited to, statements that relate to the advancement and development of BXCL501 and BXCL701, the commencement of clinical trials, the availability of data from clinical trials and other information that is not historical information. When used herein, words such as "anticipate", "being", "will", "plan", "may", "continue", and similar expressions are intended to identify forward-looking statements. In addition, any statements or information that refer to expectations, beliefs, plans, projections, objectives, performance or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking. All forward-looking statements are based upon BioXcel's current expectations and various assumptions. BioXcel believes there is a reasonable basis for its expectations and beliefs, but they are inherently uncertain. BioXcel may not realize its expectations, and its beliefs may not prove correct. Actual results could differ materially from those described or implied by such forward-looking statements as a result of various important factors, including, without limitation, market conditions and the factors described under the caption "Risk Factors" in BioXcel's prospectus dated March 7, 2018, and BioXcel's other filings made with the Securities and Exchange Commission. Consequently, forward-looking statements should be regarded solely as BioXcel's current plans, estimates and beliefs. Investors should not place undue reliance on forward-looking statements. BioXcel cannot guarantee future results, events, levels of activity, performance or achievements. BioXcel does not undertake and specifically declines any obligation to update, republish, or revise any forward-looking statements to reflect new information, future events or circumstances or to reflect the occurrences of unanticipated events, except as may be required by law.*

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### **BIOXCEL THERAPEUTICS, INC. BALANCE SHEETS**

(amounts in thousands, except shares and per share data)

	<b>March 31, 2018</b>	<b>December 31, 2017</b>
	<b>(unaudited)</b>	
<b>ASSETS</b>		
Current assets		
Cash	\$ 55,465	\$ 887
Prepaid expenses and current other assets	808	3
Due from Parent	44	-
Total current assets	56,317	890
Deferred offering expenses	-	461
Equipment, net	4	4
<b>Total assets</b>	<b>\$ 56,321</b>	<b>\$ 1,355</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		

Current liabilities		
Accounts payable	\$ 3,935	\$ 444
Accrued expenses	267	1,015
Due to related party	13	-
Payable to Parent for services	-	67
Notes payable to Parent	-	371
Due to Parent	-	440
Total current liabilities	4,215	2,337
<b>Total liabilities</b>	<b>4,215</b>	<b>2,337</b>
<b>Commitments and contingencies</b>	-	-
<b>Stockholders' equity (deficit)</b>		
Preferred stock, \$0.001 par value, 10,000,000 shares authorized; no shares issued or outstanding	-	-
Common stock, \$0.001 par value, 50,000,000 shares authorized; 15,645,545 and 9,907,548 shares issued and outstanding as of March 31, 2018 and December 31, 2017 respectively	16	10
Additional paid-in-capital	60,822	3,458
Accumulated deficit	(8,732 )	(4,450 )
Total stockholders' equity (deficit)	52,106	(982 )
<b>Total liabilities and stockholders' equity (deficit)</b>	<b>\$ 56,321</b>	<b>\$ 1,355</b>

**BIOXCEL THERAPEUTICS, INC.**  
**STATEMENTS OF OPERATIONS**  
(amounts in thousands, except shares and per share data)  
(unaudited)

	<u>Three Months Ended March 31,</u>	
	<u>2018</u>	<u>2017</u>
Net sales	\$ -	\$ -
Operating costs and expenses		
Research and development	2,938	321
General and administrative	1,348	208
Total operating expenses	4,286	529
Loss from operations	(4,286 )	(529 )
Interest income, net	4	-
Net loss	\$ (4,282 )	\$ (529 )
Net loss per share attributable to common stockholders/Parent basic and diluted	\$ (0.37 )	\$ (0.06 )
Weighted average shares outstanding - basic and diluted	11,456,325	9,480,000

**BIOXCEL THERAPEUTICS, INC.**  
**STATEMENTS OF CASH FLOWS**  
(amounts in thousands)  
(unaudited)

**Three Months Ended March**  
**31,**

<u>2018</u>	<u>2017</u>
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<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
<b>Net loss</b>	\$ (4,282 )	\$ (529 )
<b>Reconciliation of net loss to net cash used in operating activities:</b>		
Depreciation and amortization	-	1
Stock-based compensation expense	1,319	107
Changes in operating assets and liabilities:		
Prepaid expenses	(805 )	1
Accounts payable and accrued expenses	2,743	(11 )
Due to related party	13	-
Net cash used in operating activities	(1,012 )	(431 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of common stock, net	56,512	-
Net Parent investment	-	431
Payable to Parent for services	(67 )	-
Due to Parent	(484 )	-
Proceeds from note payable – Parent	(371 )	-
Net cash provided by financing activities	55,590	431
Net increase in cash	54,578	-
Cash, beginning of the period	887	-
<b>Cash at March 31, 2018</b>	<b>\$ 55,465</b>	<b>\$ -</b>
Supplemental cash flow information:		
Interest paid	\$ 2	-
Supplemental disclosure of non-cash Financing Activity:		
Deferred issuance costs reclassified to additional paid-in-capital upon completion of initial public offering	\$ 461	-

Source: BioXcel Therapeutics, Inc.