August 9, 2016

Tobira Therapeutics Reports Second Quarter 2016 Financial and Business Results

-Guest Speaker Arun Sanyal, M.D. to Speak on CENTAUR Study and NASH Landscape-

-Conference Call to be Held Today at 4:30 p.m. Eastern Time-

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)-- Tobira Therapeutics, Inc. (NASDAQ: TBRA) a clinical-stage biopharmaceutical company focused on developing and commercializing therapies for non-alcoholic steatohepatitis (NASH) and other liver diseases, today reported business highlights and financial results for the three months ended June 30, 2016.

"We are excited about the results of the CENTAUR trial, which we believe is the first study to prospectively meet an endpoint recommended for Phase 3 studies to support marketing authorization, namely ‘an improvement in fibrosis by at least one stage without worsening of NASH.' This is an important milestone as fibrosis is a key predictor of mortality and liver-related events. We are confident about our path forward, and we look forward to discussing the Phase 3 study with regulators and presenting the CENTAUR data at a medical meeting later this year," said Laurent Fischer, M.D., chief executive officer of Tobira. "On the strength of the fibrosis data, we are also advancing our NASH program with a Phase 1 trial of cenicriviroc in combination with evogliptin, which is targeted at the metabolic abnormalities implicated in NASH and complements CVC."

Recent Progress

- Reported topline data from the CENTAUR Phase 2b study showing that cenicriviroc (CVC) demonstrated a clinically relevant and statistically significant improvement in fibrosis of at least one stage without worsening of NASH, after only one year of treatment.
- Reported the publication of data showing CVC reduces inflammation and fibrosis in animal models of chronic liver and kidney disease, including NASH.
- Reported in the journal *Hepatology* that CVC is hepato-protective and reduces liver injury.
- Entered into a license agreement with Dong-A ST Co., Ltd to acquire the exclusive rights to develop and market evogliptin (EVO) in the United States, Canada, the European Union, Switzerland and Australia.

Upcoming Target Milestones

- Complete Phase 3 planning for CVC in the second half of 2016, including an end-of-Phase 2 meeting with the FDA.
- Plan to present CENTAUR Phase 2b data at a major medical meeting later this year.
- Initiate Phase 1 study of evogliptin in combination with CVC in late 2016.
- Initiate a Phase 3 program for CVC in NASH in 2017.
- Report the PERSEUS Phase 2a proof-of-concept data in primary sclerosing cholangitis (PSC) in 2017.
- Start enrollment of a Phase 2 proof-of-concept CVC + EVO combination study in NASH in 2017.

Second Quarter 2016 Financial Results

- Research and development expenses in the second quarter of 2016 were $10.9 million compared to $6.6 million in the second quarter of 2015. The increase is primarily associated with increased clinical and manufacturing expenses resulting from clinical production as well as payment of the evogliptin license fee.
- General and administration expenses in the second quarter of 2016 were $3.1 million compared to $3.1 million in the first quarter of 2015.
- Cash used in operations in the second quarter of 2016 was $11.6 million.
- Net loss for the second quarter of 2016 was $13.3 million, or $0.71 per share compared with a net loss of $11.0 million, or $0.99 per share for the same period in 2015.

2016 Six-Month Results

- Research and development expenses were $19.6 million in the first six months of 2016, compared to $12.3 million in the first six months of 2015.
- General and administration expenses were $6.5 million in the first six months of 2016, compared to $5.3 million in the first six months of 2015.
- Cash used in operations in the first six months of 2016 was $21.7 million.
- Net loss for the first six months of 2016 was $25.6 million, or $1.36 per share compared with a net loss of $18.0 million, or $3.14 per share for the same period in 2015.

Cash, Cash Equivalents & Restricted Cash

As of June 30, 2016, Tobira had cash, cash equivalents, and restricted cash of $41.0 million.

Conference Call Information

The company will host a conference call today to review Tobira's business highlights and financial results for the first quarter of 2016 beginning at 1:30 p.m. Pacific Time / 4:30 p.m. Eastern Time. Analysts and investors can participate in the conference call by dialing +1 (855) 638-8858 for domestic callers and +1 (707) 294-1299 for international callers, using the conference ID# 59149594. The webcast can be accessed live on the Investor Relations page of Tobira's website, http://ir.tobiratx.com and will be available for replay for 30 days following the call.

About the CENTAUR Study

The CENTAUR study (NCT02217475) is a Phase 2b multinational, randomized, double-blind study comparing CVC to placebo for the treatment of NASH in adults with liver fibrosis. The trial enrolled 289 patients, all with moderate to advance fibrosis (F1-F3). The primary endpoint was improvement of NAFLD Activity Score at the one year time point. The two key secondary endpoints included: ‘complete resolution of steatohepatitis and no worsening of fibrosis' (worsening defined as progression of NASH CRN fibrosis stage) and ‘improvement in liver fibrosis by at least one stage with no worsening of steatohepatitis' (no worsening of lobular inflammation or hepatocellular ballooning grade). In July 2016, Tobira announced that CENTAUR met the key secondary endpoint of improvement in liver fibrosis by at least one stage with no worsening of steatohepatitis after one year of treatment, which was recommended by regulators as an endpoint for Phase 3 studies to support a marketing application. The CENTAUR study continues for a second year analysis of endpoints, which is expected in the third quarter of 2017.

CENTAUR exclusively enrolled adults at increased risk of progression to cirrhosis. Of the 289 patients enrolled the majority (67%) had moderate (F2) to severe fibrosis (F3), the population that currently evaluate in contemporary Phase 3 studies.

About Cenicriviroc (CVC)

CVC is an oral, once-daily, potent immunomodulator that blocks two chemokine receptors, CCR2 and CCR5, which are intricately involved in the inflammatory and fibrogenic pathways in NASH that cause liver damage and often lead to cirrhosis, liver cancer, or liver failure. Because of this unique mechanism of action, targeting two of the main engines driving NASH, CVC has the potential to play a differentiated role in the management of NASH and may form the cornerstone of NASH combination treatment strategies, both as a single agent and in combination with other agents targeting metabolic pathways. CVC has been granted Fast Track status in patients with NASH and liver fibrosis, the patient population at highest risk of progression to cirrhosis.

In addition to CENTAUR, CVC is also being evaluated in the PERSEUS study (identifier NCT02653625), a Phase 2 proof-of-concept study of CVC in patients with primary sclerosing cholangitis, a rare inflammatory liver disease.

About Non-Alcoholic Steatohepatitis (NASH)

NASH is a severe type of non-alcoholic fatty liver disease (NAFLD), which is characterized by the accumulation of fat in the liver with no other apparent causes. NASH occurs when the accumulation of liver fat is accompanied by inflammation and cellular damage. The inflammation can lead to fibrosis (scarring) of the liver and eventually progress to cirrhosis, portal hypertension, liver cancer, and eventual liver failure.

NASH is an emerging health crisis impacting 3% to 5% of the U.S. population and 2% to 4% globally, and is the fastest growing cause of liver cancer and liver transplant in the U.S. The increasing prevalence of NASH is attributed to the growing obesity epidemic and the disease is often diagnosed in patients who have diabetes, high cholesterol or high triglycerides.

There is currently no approved treatment for NASH.

About Tobira Therapeutics

Tobira is a clinical-stage biopharmaceutical company focused on the development and commercialization of therapies for non-alcoholic steatohepatitis (NASH) and other liver diseases. The company's lead product candidate, cenicriviroc (CVC), is a first-in-class immunomodulator and dual inhibitor of CCR2 and CCR5 in late-stage development for the treatment of NASH, a serious liver disease that can progress to cirrhosis, liver cancer and liver failure. CVC is also being investigated to address primary sclerosing cholangitis (PSC), a disease which causes inflammation and scarring of the bile ducts, eventually leading to serious liver damage. Tobira's pipeline also includes evogliptin, a selective DPP-4 inhibitor, which it plans to develop for NASH in combination with CVC. Learn more about Tobira at www.tobiratx.com.

Tobira® is a registered trademark owned by Tobira Therapeutics, Inc.

Forward Looking Statements

This release contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements reflect management's current knowledge, assumptions, judgment and expectations regarding future performance or events. Although management believes that the expectations reflected in such statements are reasonable, they give no assurance that such expectations will prove to be correct and you should be aware that actual results could differ materially from those contained in the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties including, but not limited to, the company's clinical development of cenicriviroc (CVC) and evogliptin (EVO); the potential timing and outcomes of clinical studies of Tobira's product candidates undertaken now or in the future; the ability of the company to timely source adequate supply of its development products from third party manufacturers on whom the company depends; the company's limited cash reserves and its ability to obtain additional capital on acceptable terms, or at all; the company's ability to successfully progress, partner or complete further development of its programs; the uncertainties inherent in clinical testing; the timing, cost and uncertainty of obtaining regulatory approvals; the company's ability to protect its intellectual property; competition; changes in the regulatory landscape or the imposition of regulations that affect the company's products; and other factors listed under "Risk Factors" in the company's other filings with the Securities and Exchange Commission.

TOBIRA THERAPEUTICS, INC.
CONDENSED BALANCE SHEETS
(In thousands)

	June 30, 2016 (Unaudited)	December 31, 2015 [1]
Assets		
Current assets:		
Cash and cash equivalents	$ 40,692	$ 62,431
Other current assets	1,702	802
Total current assets	42,394	63,233
Restricted cash	334	334
Other assets	1,913	1,841
Total assets	$ 44,641	$ 65,408
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,232	$ 3,089
Accrued expenses and other liabilities	5,267	4,263
Term loan	2,523	—
Other current liabilities	80	71
Total current liabilities	12,102	7,423
Term loan	12,624	15,013
Other liabilities	157	201
Total liabilities	24,883	22,637
Total stockholders' equity	19,758	42,771

Total liabilities and stockholders' equity	$ 44,641	$ 65,408

(1) Derived from audited financial statements

TOBIRA THERAPEUTICS, INC.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)
(In thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
License and collaboration revenue	$ 1,058	$ —	$ 1,165	$ —
Operating expenses:				
Research and development	10,880	6,616	19,559	12,287
General and administrative	3,128	3,119	6,469	5,271
Total operating expenses	14,008	9,735	26,028	17,558
Loss from operations	(12,950)	(9,735)	(24,863)	(17,558)
Other income (expense), net:				
Interest expense, net	(310)	(1,190)	(618)	(2,435)
Change in fair value of preferred stock warrant liabilities	—	(97)	—	1,939
Loss before income tax (expense) benefit	(13,260)	(11,022)	(25,481)	(18,054)
Income tax benefit (expense)	(83)	35	(83)	35
Net loss and comprehensive loss	$ (13,343)	$ (10,987)	$ (25,564)	$ (18,019)
Net loss per common share, basic and diluted	$ (0.71)	$ (0.99)	$ (1.36)	$ (3.14)
Weighted-average common shares outstanding, basic and diluted	18,815,689	11,124,751	18,815,689	5,733,406

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