
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): March 9, 2017

Dimension Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

DELAWARE
(State or other jurisdiction
of incorporation)

001-37601
(Commission
File Number)

46-3942159
(I.R.S. Employer
Identification No.)

840 Memorial Drive, 4th Floor
Cambridge, MA
(Address of principal executive offices)

02139
(Zip Code)

Registrant's telephone number, including area code (617) 401-0011

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 2.02. Results of Operations and Financial Condition.

On March 9, 2017, Dimension Therapeutics, Inc. (the “Company”) issued a press release regarding its financial and operating results for the year ended December 31, 2016. A copy of the Company’s press release is furnished as Exhibit 99.1 to this report on Form 8-K.

The following information and Exhibit 99.1 attached hereto shall not be deemed “filed” for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by the Company on March 9, 2017, furnished herewith.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: March 9, 2017

DIMENSION THERAPEUTICS, INC.

By: /s/ Jean Franchi

Jean Franchi
Chief Financial Officer

Dimension Therapeutics Announces Full Year 2016 Financial Results and Recent Updates Across Rare and Metabolic Disease Portfolio and in HeLa Manufacturing

In December, initiated Phase 1/2 clinical trial of DTX301, Dimension's lead IMD product candidate for OTC Deficiency; Initial data expected 2H 2017

Updates interim results from Phase 1/2 clinical program for DTX101 in hemophilia B

Conference call today at 8:30 a.m. Eastern Time

CAMBRIDGE, Mass., March 9, 2017 — Dimension Therapeutics, Inc. (NASDAQ:DMTX), a biopharmaceutical company advancing novel, adeno-associated virus (AAV) gene therapies targeting the liver, a key organ for human metabolism, today provided updated interim results from the Company's Phase 1/2 clinical program of DTX101 for the treatment of adult patients with moderate/severe to severe hemophilia B. In addition, Dimension today reported financial results for the full year ended December 31, 2016 and provided an update on the Company's recent corporate progress across its portfolio of inherited metabolic disease (IMD) programs.

"During 2016, we further advanced the science and manufacturing of AAV-based gene therapy including the continued development of our next generation HeLa 2.0 platform and initiated our global Phase 1/2 clinical trial for DTX301, our lead IMD product candidate for the treatment of ornithine transcarbamylase (OTC) deficiency," said Annalisa Jenkins, MBBS, FRCP, Chief Executive Officer of Dimension. "We also continue to explore options for DTX101 as our data mature, while remaining laser-focused on maximizing the value of our portfolio. We are dedicated to advancing these and other key programs in order to bring hope to patients and their families living with rare genetic diseases associated with the liver."

DTX101 Phase 1/2 Clinical Program

DTX101 is designed to deliver stable expression of blood clotting Factor IX (FIX) in patients with hemophilia B, a rare genetic bleeding disorder resulting from a deficiency in FIX. In the Phase 1/2 open-label study, patients received a capsid serotype AAVrh10 vector with a codon-optimized FIX gene expressing wild-type FIX protein. In January 2017, the Company completed dosing in the first two cohorts (Cohort 1: N=3, 1.6×10^{12} GC/kg; Cohort 2: N=3, 5×10^{12} GC/kg) and reported interim topline data. All patients in both cohorts improved from moderate/severe-to-severe to either moderate or mild range in terms of factor levels based on World Federation of Hemophilia (WFH) criteria. In addition, none of the patients in cohort 2 have required prophylactic or on-demand recombinant FIX transfusion for spontaneous bleeds post-dosing. As required by the clinical trial protocol, the Company reported the ALT levels for patient 3 in cohort 2 to the Data Safety Monitoring Committee (DSMC), the U.S. Food and Drug Administration (FDA), and other appropriate regulatory authorities, and remains in ongoing communications. Dimension will await feedback prior to initiating dosing of Cohort 3.

Clinical Update:

- Patients in the two cohorts have now been in post-treatment follow-up ranging from 11 to 52 weeks. Evidence of high efficiency liver transduction of the AAVrh10 vector continues to be observed across the two patient cohorts.
- As previously reported, patients in the second dose cohort achieved peak FIX expression of 13%, 20%, and 12% at weeks 4, 8, and 8, respectively. As of the February 28, 2017 data cutoff, FIX activity was 5% and 10% in two patients at 16-weeks follow-up, and 10% for the third patient at 11 weeks. For the low-dose cohort, expression levels achieved peak levels of 10-11%, stabilizing between 3-4% at last follow-up on February 28, 2017 (weeks 28, 52, and 52).
- As previously reported, subclinical elevations in alanine aminotransferase, or ALT, were observed in 5 of 6 patients, with patient 3 in cohort 2 experiencing a grade 4 adverse event due to an elevated laboratory ALT defined as greater than 800 IU/L. As of the February 28, 2017 data cutoff, the ALT level in the patient 3 in cohort 2 has dropped to 116 IU/L at 11 weeks post-dosing and appears to be responding to a standard tapering course of corticosteroids. The other two patients in cohort 2 also continue on steroids, and their ALT levels are in the normal range, as are those in cohort 1.
- Asymptomatic transient elevations in liver enzymes observed in patients 1 and 2 from cohort 2 were associated with a mild T-cell response to the capsid, corresponding to elevations in liver enzymes and declines in FIX activity.
- Substantial analyses were carried out on samples from the third patient in cohort 2 to characterize and determine the potential immunological basis for the subclinical ALT elevation. As of the February 28, 2017 data cutoff, there is no evidence that the elevation was caused by an immune response to the capsid or transgene. Studies are ongoing to explore further causes for ALT elevation in this patient, including other immune and non-immune effects, and the role of a rare HLA genotype present in this patient.

“The encouraging clinical data from Dimension’s lead program are supported by what we have seen in our patients who participated in the study, many of whom have anecdotally related the positive impact of therapy on their well-being. These data add to the growing body of evidence that restoration of clotting function may be achieved by gene therapy,” said Dr. Steven Pipe, Director of the Division of Pediatric Hematology and Oncology and Pediatric Medical Director of the Hemophilia and Coagulation Disorders Program at the C.S. Mott Children’s Hospital of the University of Michigan, and the lead investigator on the clinical trial. “I look forward to the further progress of the clinical program, which has demonstrated the potential for patients to avoid bleeding and to have options that potentially minimize or eliminate the need for infusions of factor concentrates.”

Other Recent Highlights and Upcoming Milestones

- **IMD Portfolio:** Continued to advance multiple lead IMD candidates utilizing the capsid serotype AAV 8 - DTX301 for OTC deficiency, DTX401 for GSDIa, DTX501 for PKU, DTX701 for Wilson disease, and DTX601 for citrullinemia type I:
 - **DTX301:** IND accepted in December 2016 and initiated a multi-center Phase 1/2 open-label study for lead IMD candidate DTX301 in December 2016. Two sites open and expect to disclose initial data from the trial in the second half of 2017.

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- Includes assessment of ^{13}C -acetate to evaluate rate of ureagenesis and hepatocyte (liver) ureagenesis capacity.
 - **DTX401:** Advancing IND-enabling activities to support an IND filing for DTX401 by the end of 2017.
 - In November 2016, received a positive opinion from the European Medicines Agency (EMA) Committee for Orphan Medicinal Products (COMP) recommending DTX401 for designation as an orphan medicinal product for the treatment of GSD1a.
 - **DTX501, DTX701, DTX601:** Ongoing nonclinical activities supporting selection of development candidates for Wilson disease (DTX701) and for PKU (DTX501) in 2H 2017 and for citrullinemia type I (DTX601) in the next 12-18 months.
 - **DTX201:** Currently in IND-enabling studies in collaboration with Bayer for the treatment of moderate/severe to severe hemophilia A.
 - IND filing for DTX201 expected by the end of 2017.
 - **HeLa Manufacturing:** Significantly advanced HeLa mammalian cell-based suspension platform for DTX201.
 - Locked lab scale manufacturing process, successfully transferred upstream process, and initiated tech transfer for clinical supply at GMP scale at a CMO.
 - **Corporate:** Elected John A. Hohneker, M.D., Executive Vice President, Head of Research and Development of FORMA Therapeutics Inc., to Board of Directors.
 - Dr. Hohneker brings over 25 years' global experience in pharmaceutical drug development across diverse therapeutic areas to address substantial unmet needs.

Full Year 2016 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities as of December 31, 2016 were \$78.0 million, compared with \$127.0 million on December 31, 2015. The Company expects its existing cash, cash equivalents, and marketable securities, and reimbursements and milestones to be received in connection with its collaboration agreement with Bayer, and borrowing capacity under its loan and security agreement with Silicon Valley Bank will enable it to fund its operating expenses and capital expenditure requirements through mid-2018.
- **Revenue:** For the year ended December 31, 2016, Dimension recognized \$11.5 million of revenue associated with our collaboration agreement with Bayer, compared to \$7.8 million for the same period in 2015. The increase was due to services performed in connection with its performance obligations under the collaboration agreement with Bayer.
- **R&D Expenses:** Research and development expenses, were \$47.7 million, including \$1.2M non-cash stock based compensation expense, for the year ended December 31, 2016, compared to \$34.0 million, including \$0.7M non-cash stock based compensation expense, for the same period in 2015. The increase was largely due to expenditures incurred in process development, manufacturing activities, IND enabling activities and early clinical development of DTX301, advancing preclinical development of the company's pipeline, process development and manufacturing activities of DTX401 and personnel costs associated with the growth of the company (including non-cash stock-based compensation).

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- **G&A Expenses:** General and administrative expenses were \$12.8 million, including \$2.2M non-cash stock based compensation expense, for the year ended December 31, 2016, compared to \$8.7 million, including \$0.7M non-cash stock based compensation expense, for the same period in 2015. The increase was largely due to the full year impact of expenditures in personnel (including non-cash stock-based compensation) hired in late 2015 and increased expenditures in legal fees, business insurance and general operations in the company's first full year of operating as a public company.
 - **Net Loss:** The Company reported a net loss of \$(49.0) million, or \$(1.97) per share, for the year ended December 31, 2016, compared to a net loss of \$(35.1) million, or \$(4.41) per share, for the year ended December 31, 2015.

About the Hemophilia B Phase 1/2 Program

Dimension's phase 1/2 clinical trial of DTX101 is a single arm, open-label, multi-center study, designed to evaluate the safety, dose, and early efficacy of DTX101 in adult patients with moderate/severe to severe hemophilia B. Patients enrolled in Cohorts 1 and 2 range in age from 28 to 70 years, demonstrating baseline FIX expression of $\leq 2\%$ that requires either prophylactic or on demand recombinant FIX transfusion. Dimension is continuing to explore underlying demographics and patient characteristics to optimize dosing of DTX101.

Additional information about Dimension's Phase 1/2 study of DTX101 may be found at ClinicalTrials.gov, using Identifier NCT: NCT02618915.

Conference Call Information

Dimension Therapeutics will host a live conference call and webcast today, March 9, 2017 at 8:30 a.m. Eastern Time. Members of the Company's management team will also be joined by Dr. Steven Pipe, Director of the Division of Pediatric Hematology and Oncology and Pediatric Medical Director of the Hemophilia and Coagulation Disorders Program at the C.S. Mott Children's Hospital of the University of Michigan.

The live webcast can be accessed by visiting the investor relations section of the Dimension Therapeutics website at www.dimensiontx.com. Please connect to the Company's website at least 15 minutes prior to the live webcast to ensure adequate time for any software download that may be needed to access the webcast. Alternatively, please call 844-804-8784 (U.S.) or 210-229-8833 (International) to listen to the conference call. The conference ID number for the live call will be 84164743. An archive of the webcast will be available until March 23, 2017 on the investor relations section of the Company's website.

About Dimension Therapeutics, Inc.

Dimension Therapeutics, Inc. (NASDAQ:DMTX) is a leader in discovering and developing new therapeutic products for people living with devastating rare and metabolic diseases associated with the liver, based on the most advanced mammalian adeno-associated virus (AAV) gene delivery technology. Dimension is actively progressing its broad pipeline, which features programs addressing unmet needs for patients suffering from inherited metabolic diseases, including OTC deficiency, GSDIa, citrullinemia type 1, PKU, Wilson disease, a collaboration with Bayer in hemophilia A, and a wholly owned clinical program in hemophilia B. Dimension has two phase 1/2 clinical trials for the treatment of hemophilia B and OTC deficiency. The company targets diseases with readily identifiable patient populations, highly predictive preclinical models, and well-described, and often clinically validated, biomarkers. Founded in 2013, Dimension maintains headquarters in Cambridge, Massachusetts.

For more information, please visit www.dimensiontx.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding the development, preclinical and clinical results, upcoming milestones, the potential productivity of Dimension’s ongoing collaborations and the continued progress of Dimension’s portfolio and programs, including the initiation, timing, scope, or likelihood of regulatory filings and approvals, and our ability to develop and advance product candidates into, and successfully complete, clinical studies. All such forward-looking statements are based on management’s current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include the risks that Dimension’s product candidates, including its candidates, DTX101 and DTX301, will not successfully be developed or commercialized in the times indicated or at all; the impact of the observed data in Cohorts 1 and 2, including the adverse event described above and any later safety event on timing, dosing, regulatory action or patient enrollment with respect to DTX101 and DTX301; and the risks described under the caption “Risk Factors” in Dimension Therapeutics’ Annual Report on Form 10-K for the year ended December 31, 2016, which is on file with the Securities and Exchange Commission, as well as other risks detailed in Dimension Therapeutics’ additional filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and Dimension Therapeutics undertakes no duty to update this information unless required by law.

DIMENSION THERAPEUTICS, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share amounts)

	December 31,	
	2016	2015
Assets		
Current assets:		
Cash and cash equivalents	\$ 30,234	\$127,047
Marketable securities	47,715	—
Accounts receivable	1,885	143
Prepaid expenses and other current assets	5,484	2,740
Total current assets	85,318	129,930
Property and equipment, net	8,402	3,339
Deferred offering costs	145	—
Total assets	<u>\$ 93,865</u>	<u>\$133,269</u>
Liabilities, Convertible Preferred Stock and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,368	\$ 1,555
Accrued expenses and other current liabilities	7,247	3,715
Amounts due to related parties	—	522
Deferred revenue	8,663	6,835
Notes payable	2,361	574
Total current liabilities	20,639	13,201
Deferred revenue, net of current portion	8,663	13,670
Notes payable, net of discount and current portion	4,169	759
Other liabilities	453	56
Total liabilities	<u>33,924</u>	<u>27,686</u>
Commitments and contingencies [(Note 15)]		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 5,000,000 shares authorized at December 31, 2016 and 2015; zero shares issued or outstanding at December 31, 2016 and 2015.	—	—
Common stock, \$0.0001 par value; 150,000,000 shares authorized as of December 31, 2016 and 2015; 25,043,506 and 25,008,227 shares issued and outstanding as of December 31, 2016 and 2015, respectively.	2	2
Additional paid-in capital	160,185	156,775
Accumulated deficit	(100,195)	(51,194)
Accumulated other comprehensive loss	(51)	—
Total stockholders' equity	<u>59,941</u>	<u>105,583</u>
Total liabilities and stockholders' equity	<u>\$ 93,865</u>	<u>\$133,269</u>

DIMENSION THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share amounts)

	Year Ended December 31,		
	2016	2015	2014
Revenue	\$ 11,471	\$ 7,750	\$ 2,750
Operating expenses:			
Research and development	47,741	33,992	12,974
General and administrative	12,780	8,723	2,727
Total operating expenses	60,521	42,715	15,701
Loss from operations	(49,050)	(34,965)	(12,951)
Interest income (expense), net	49	(91)	(17)
Net loss	(49,001)	(35,056)	(12,968)
Accretion of convertible preferred stock to redemption value	—	(23)	(71)
Net loss attributable to common stockholders	\$ (49,001)	\$ (35,079)	\$ (13,039)
Net loss per share attributable to common stockholders — basic and diluted	\$ (1.97)	\$ (4.41)	\$ (3.61)
Weighted average common shares outstanding — basic and diluted	24,915,887	7,949,670	3,610,592
Comprehensive loss:			
Net loss	\$ (49,001)	\$ (35,056)	\$ (12,968)
Other comprehensive loss			
Unrealized loss on marketable securities	(51)	—	—
Total other comprehensive gain (loss)	(51)	—	—
Total comprehensive loss	\$ (49,052)	\$ (35,056)	\$ (12,968)

This selected financial information should be read in conjunction with the audited, condensed consolidated financial statements and notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2016.

Contacts:

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