
**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): **July 13, 2017**

Avenue Therapeutics, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

000-55558
(Commission File Number)

47-4113275
(IRS Employer Identification No.)

2 Gansevoort Street, 9th Floor
New York, New York 10014
(Address of Principal Executive Offices)

(781) 652-4500
(Registrant's telephone number, including area code)

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.
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act.
- ☐ Pre-commencement communications pursuant to Rule 14d-2b under the Exchange Act.
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act.

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

Attached hereto as Exhibit 99.1 and incorporated herein by reference is a PowerPoint presentation including a corporate overview of Avenue Therapeutics, Inc., which will be made available on its website at www.avenuetx.com.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is filed as part of this report:

Exhibit Number	Description
99.1	Company PowerPoint presentation.

SIGNATURES

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

AVENUE THERAPEUTICS, INC.
(Registrant)

Date: July 13, 2017

By: /s/ Lucy Lu, M.D.
Name: Lucy Lu, M.D.
Title: President and Chief Executive Officer

Avenue Therapeutics, Inc.

Nasdaq: ATXI

July 2017



Forward Looking Statements

Statements in this presentation that are not descriptions of historical facts are forward-looking statements within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995. We have attempted to identify forward-looking statements by terminology including “anticipates,” “believes,” “can,” “continue,” “could,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “predicts,” “should,” or “will” or the negative of these terms or other comparable terminology. Forward-looking statements are based on management’s current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock price. Factors that could cause actual results to differ materially from those currently anticipated are risks relating to: our growth strategy; results of research and development activities; uncertainties relating to preclinical and clinical testing; our dependence on third party suppliers; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; our ability to attract, integrate, and retain key personnel; the early stage of products under development; our need for substantial funds; government regulation; patent and intellectual property matters; competition; as well as other risks described in the “Risk Factors” section of our Registration Statement on Form S-1 initially filed with the Securities and Exchange Commission on April 28, 2017 as subsequently amended to date (our “Registration Statement”). We expressly disclaim any obligation or undertaking to update or revise any statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances after the date of this presentation. You should read carefully our “Special Cautionary Notice Regarding Forward-looking Statements” and the factors described in the “Risk Factors” sections of our Registration Statement to better understand the risks and uncertainties inherent in our business.



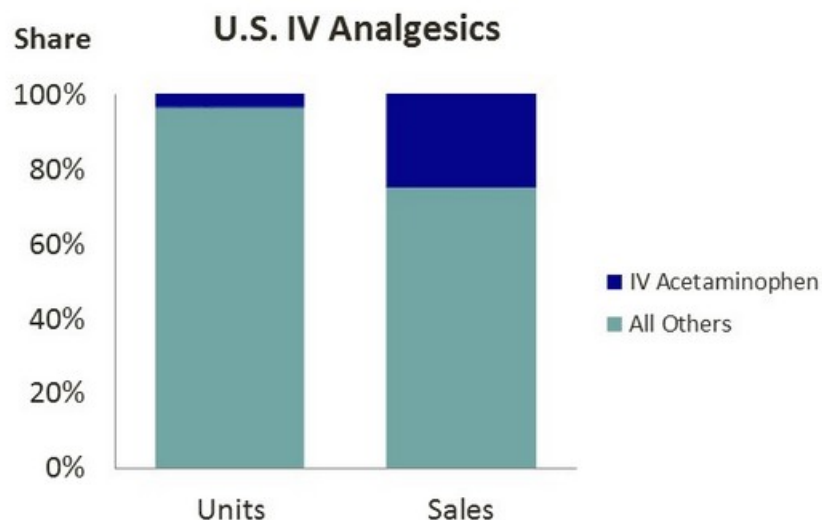
Why IV Tramadol?

- The only intravenous Schedule IV opioid in the U.S. if approved
 - Less addiction potential than widely prescribed narcotics in the hospital
- Oral tramadol has established efficacy and safety
 - Physicians are already familiar with tramadol
 - Available “step-down” therapy and no need to switch to a different drug when patients go home
 - Reduced development risk
- Entering Phase III in 3Q2017
 - Phase III data in 2Q2018



U.S. Post-Op Pain Market

- IV analgesics sold ~\$1 billion (~300 million injectable units) in 2015
- IV acetaminophen sells >\$250MM per year: >25% of total dollar market with approximately 3 to 4% of the unit volume



Source: IMS Health and Mallinckrodt Pharmaceuticals

Room for Improvement

IV Acetaminophen	IV NSAIDS	IV Narcotics
Pain Levels		
Mild to Moderate	Mild to Moderately Severe	Moderate to Severe
Common Limitations & Contraindications		
Hepatic Impairment	Bleeding risk GI Side Effects Renal Impairment	Strong Sedation Respiratory Depression Constipation Risk of Dependence



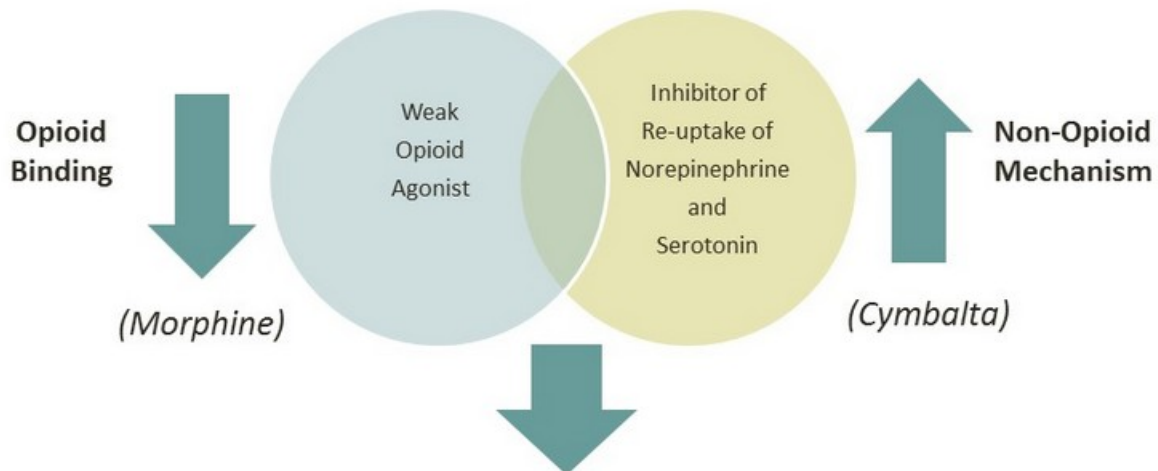
Future Post-Op Pain Management Paradigm

IV Acetaminophen	IV NSAIDS	IV Tramadol	IV Narcotics
Pain Levels			
Mild to Moderate	Mild to Moderately Severe	Moderate to Moderately Severe	Moderate to Severe
Common Limitations & Contraindications			
Hepatic Impairment	Bleeding risk GI Side Effects Renal Impairment	Nausea/Dizziness History of Seizure Concomitant use of Serotonergic Drugs	Strong Sedation Respiratory Depression Constipation Risk of Dependence



What is Tramadol

Not a typical opioid



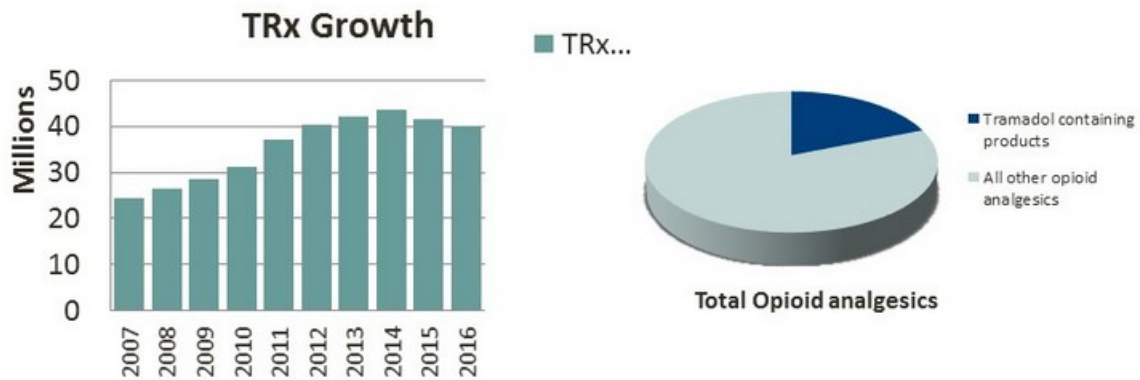
Opioid Efficacy with Less Addiction Potential



Oral Tramadol in the U.S.

Schedule IV and widely prescribed

- Approved in 1995 and labeled for “moderate to moderately severe” pain
- Prescriptions increased from 24.5 million in 2007 to over 40.0 million in 2012
- Accounts for ~20% of all opioid prescriptions



Source: Symphony Health

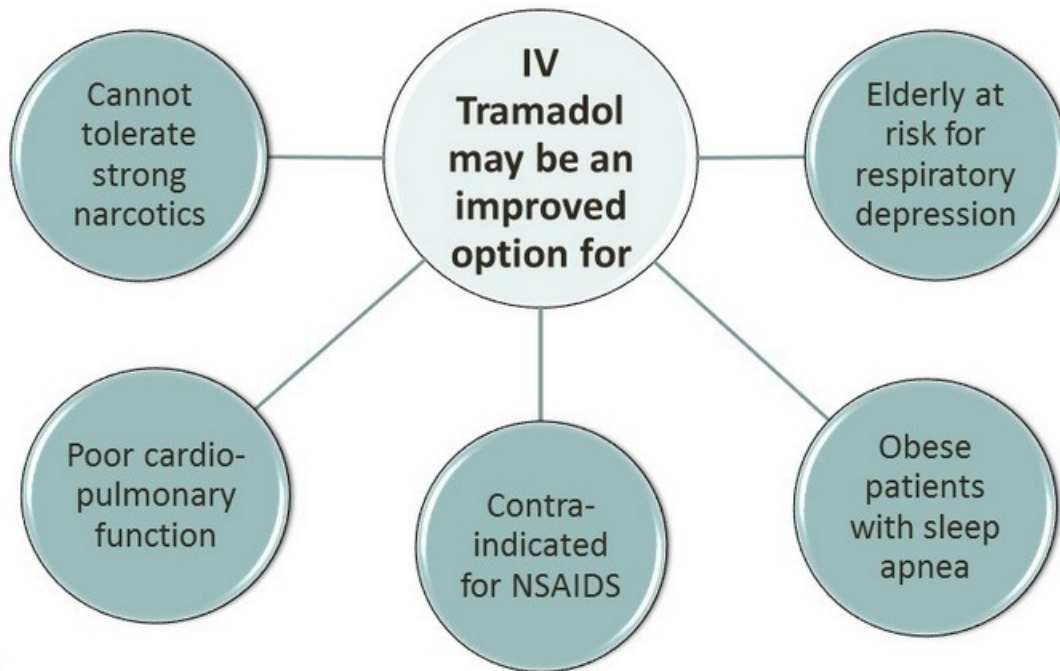
Headlines on Opioid Crisis in the U.S.

- *After Record Year for Fatal Overdoses, New York City Targets Opioids – WSJ 3/13/2017*
- *Every 45 minutes, a child is poisoned by opioids – CNBC 3/20/2017*
- *FDA nominee says nation's opioid crisis is as serious as Ebola, Zika threats – The Washington Post 4/5/2017*



IV Tramadol Opportunity

- IV tramadol may be used in all types of inpatient and outpatient surgeries and as part of a multimodal analgesic plan for major surgery



Results from a Survey of 30 U.S. Anesthesiologists*

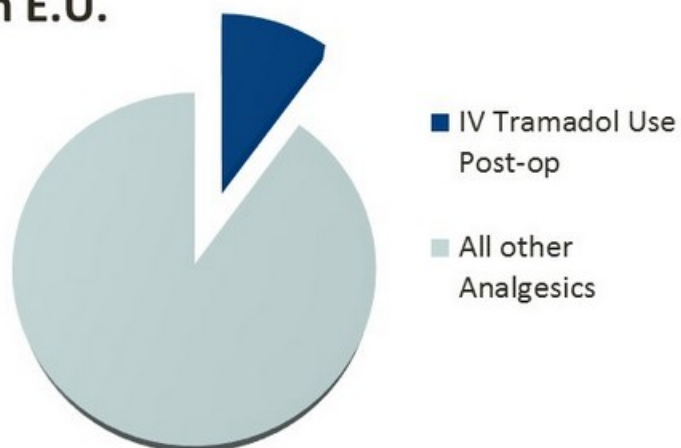
Overall Impression	
Favorable initial impression of tramadol as a potential new IV analgesic	77%

Patients taking	Switch to IV tramadol	Add IV tramadol
IV morphine	40%	41%
IV NSAIDS	26%	37%
IV acetaminophen	24%	35%

 *Survey conducted through LEERINK and available upon request

IV Tramadol Widely Used Outside the U.S.

**Accounts for ~10% of IV
analgesic use in the
post-op setting in E.U.**



Source: IMS Health

Advantages of IV Tramadol

- Oral tramadol has established efficacy and safety and physicians are familiar with it
- Less addiction potential than widely prescribed narcotics in the hospital
 - Easily fitted into multi-modal pain management to avoid conventional opioids
- Available “step-down” therapy
 - Patients can be transitioned from IV to oral tramadol

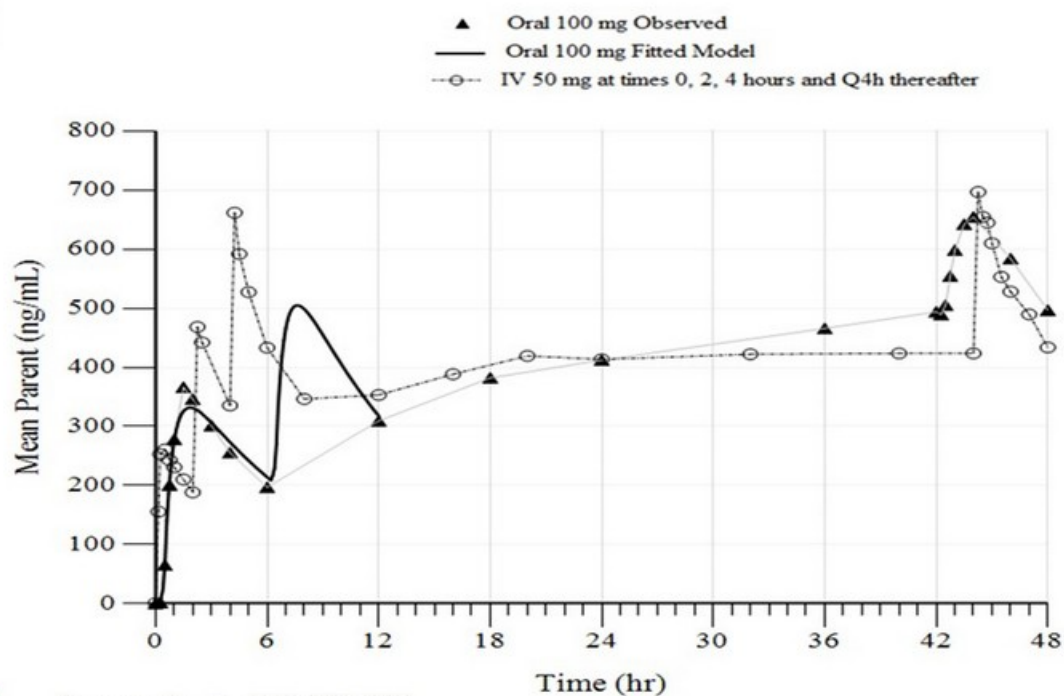


Novel Dosing Regimen

- IV tramadol 50 mg is administered at Hours 0, 2, 4, and once every 4 hours thereafter
- This dosing regimen was designed to provide a similar C_{max} and AUC to that of 100 mg oral tramadol given every 6 hours at steady state



Mean Tramadol Plasma Concentration vs. Time Curve for IV 50 mg, Oral 100 mg



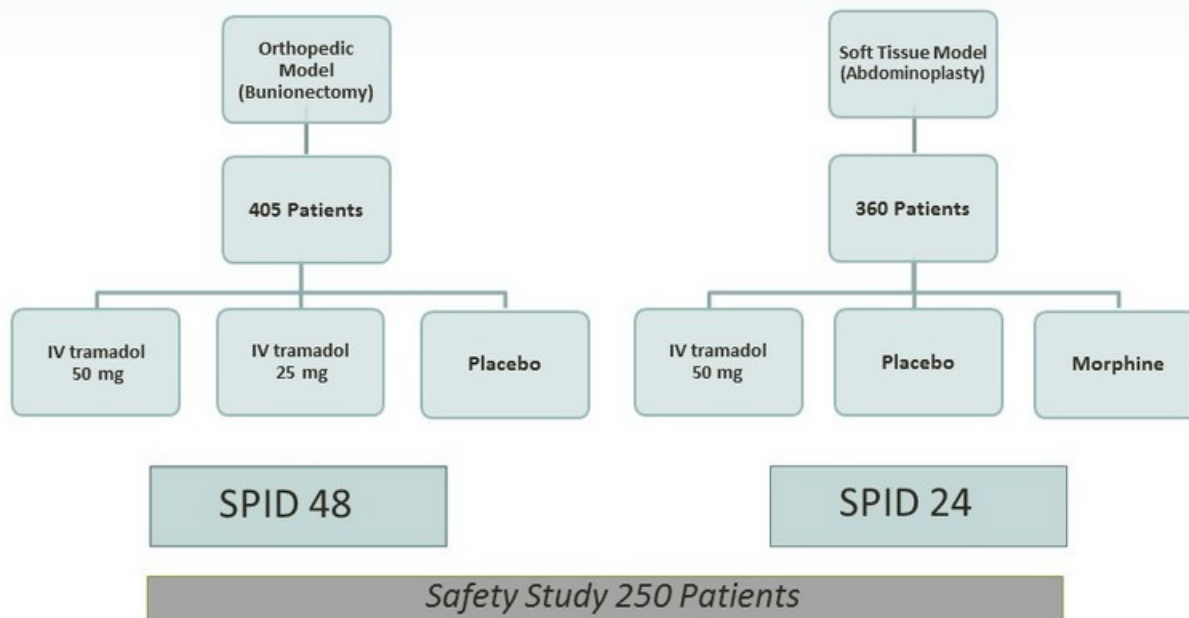
Source: Study AVE-901-101

Intellectual Property

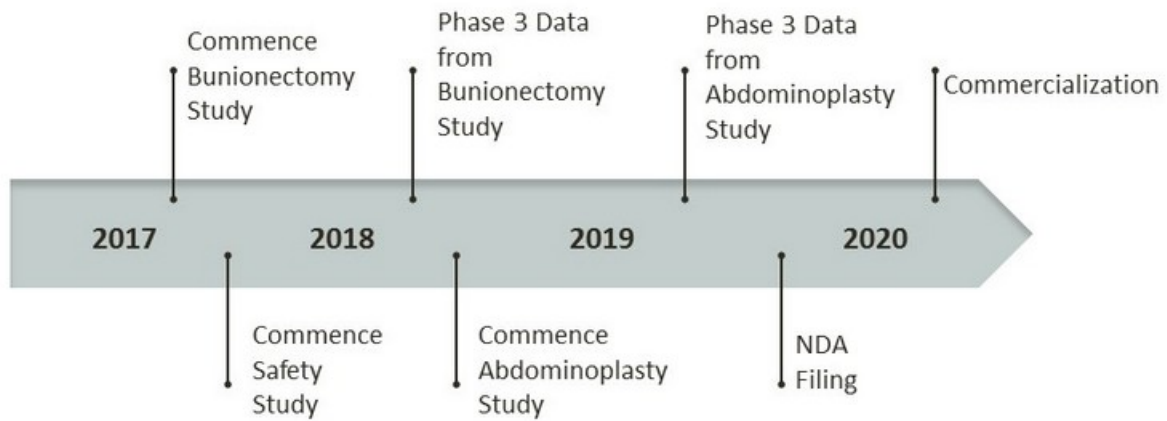
- Strong patent portfolio on *Intravenous Administration of Tramadol*
 - U.S. Patents No. 8,895,622, No. 9,561,195 and No. 9,566,253
 - U.S. Patent No. 9,693,949
 - Further Patent Applications are contemplated



Phase 3 Program



Upcoming Milestones



Detailed Calendar of Events

Initiate Phase III bunionectomy study	3Q2017
Initiate Safety study	4Q2017
Topline data from Phase III bunionectomy study	2Q2018
Initiate Phase III abdominoplasty study	3Q2018
Topline data from Phase III abdominoplasty study	2Q2019
Complete Safety study	2Q2019
Submit NDA	Year-end 2019
Commercialization	2020



Avenue Therapeutics, Inc.

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