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): **May 25, 2018**

Avenue Therapeutics, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-38114**	**47-4113275**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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 7.01 Regulation FD Disclosure.

From time to time, Avenue Therapeutics, Inc. ("Avenue") presents and/or distributes slides and presentations to the investment community to provide updates and summaries of its business. On May 25, 2018, Avenue updated its corporate presentation to include the results from its Phase 3 clinical trial of intravenous (IV) tramadol. The updated presentation is available on Avenue's website at www.avenuetx.com. This presentation is also furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this report furnished pursuant to Item 7.01 shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section. It may only be incorporated by reference in another filing under the Exchange Act or the Securities Act of 1933, as amended, if such subsequent filing specifically references the information furnished pursuant to Item 7.01 of this report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is furnished as part of this report:

Exhibit Number	Description
99.1	Corporate Presentation of Avenue Therapeutics, Inc., dated May 25, 2018.

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: May 25, 2018

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

Exhibit 99.1

AVENUE THERAPEUTICS, INC. | NASDAQ: ATXI | MAY 2018

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 Annual Report on Form 10-K for the year ended December 31, 2017 (“Form 10-K”) and other periodic reports filed from time to time with the Securities and Exchange Commission. 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 Form 10-K and other periodic reports to better understand the risks and uncertainties inherent in our business.

Developing IV Tramadol to Address Significant Unmet Need in Postoperative Pain

Uniquely Positioned to Address a Clear Need for New Therapies Amidst Opioid Crisis

- Double MOA delivers opioid efficacy with less abuse potential and risk of dependence
- Fills in the gap in acute care space between IV acetaminophen/NSAIDS and conventional narcotics
- Provides convenient bridge to widely prescribed oral tramadol, which has established efficacy and safety
- **If approved, IV Tramadol will be *the only intravenous Schedule IV opioid* in the U.S.**

Broad Applicability Translates into Substantial Market Opportunity

- A new option for patients with contraindications to NSAIDS, elderly patients at risk for respiratory depression, obese patients with sleep apnea, and those who can't tolerate strong narcotic, etc.

Validation from Positive Phase 3 Results De-risks the Program

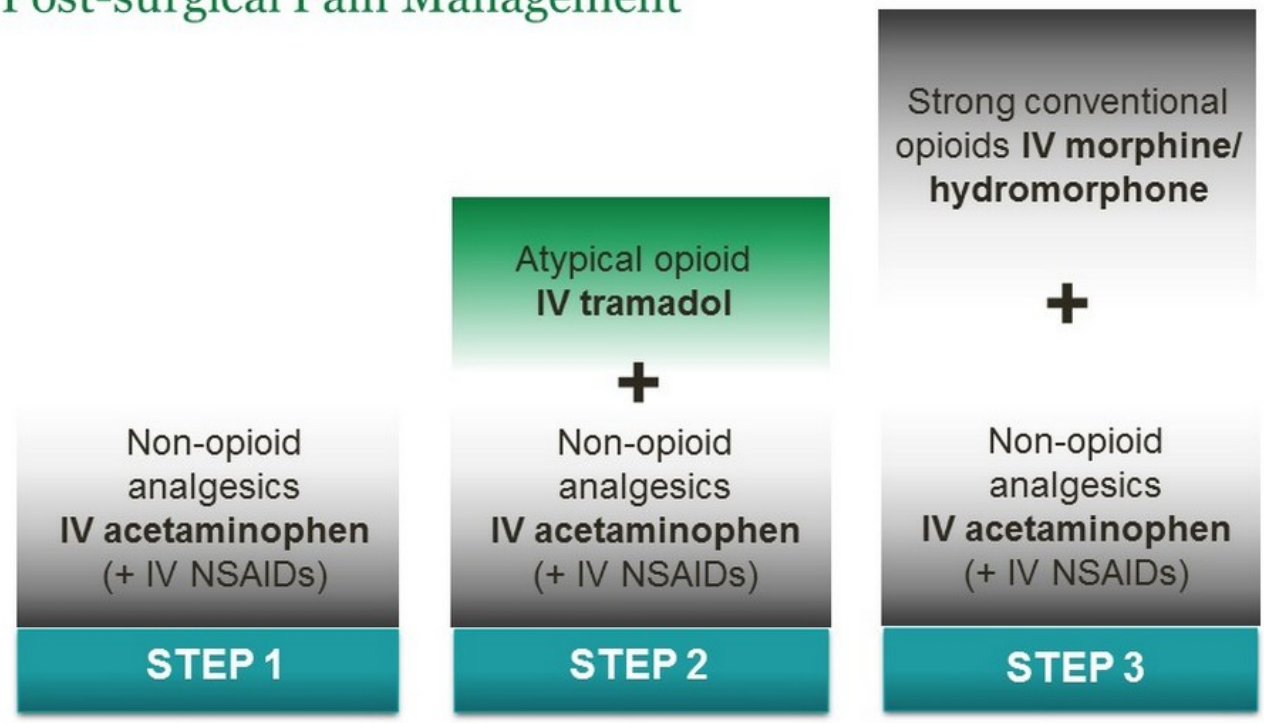
- ***IV Tramadol 50 mg met primary and all key secondary endpoints*** in patients undergoing bunionectomy surgery
- Safe and well-tolerated with no surprises
- Initiation of pivotal Phase 3 trial in patients following abdominoplasty expected 3Q18; topline data expected 2Q19 and NDA filing by year-end 2019

Strong IP Position Protects Exclusivity in the U.S. Until 2036

- Robust patent portfolio on our proprietary dosing regimen

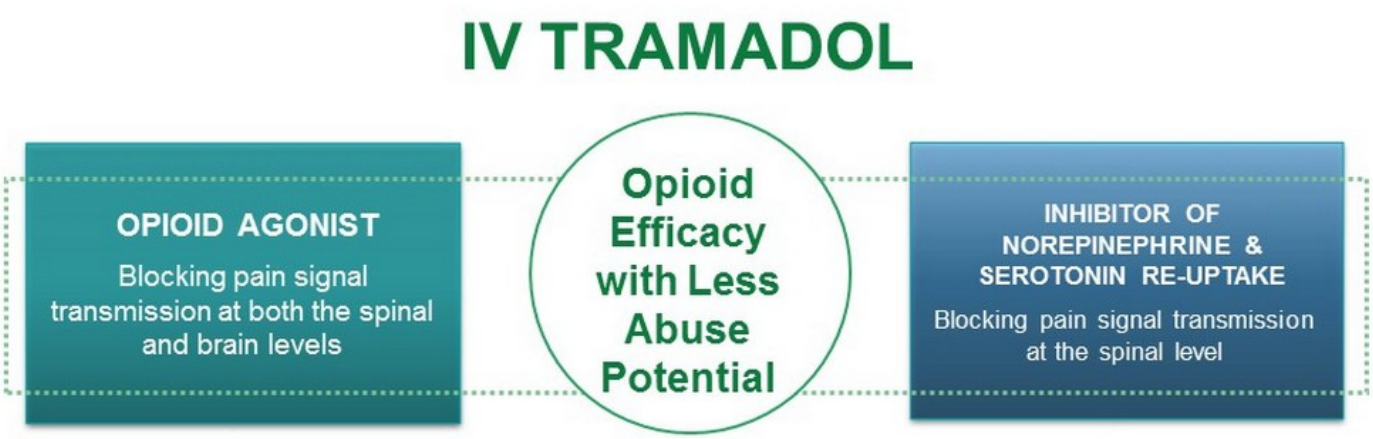
Future Paradigm: Simplified IV "Analgesic Ladder" Post-2020

Systemic Pharmacotherapy to Remain the Mainstay of Post-surgical Pain Management



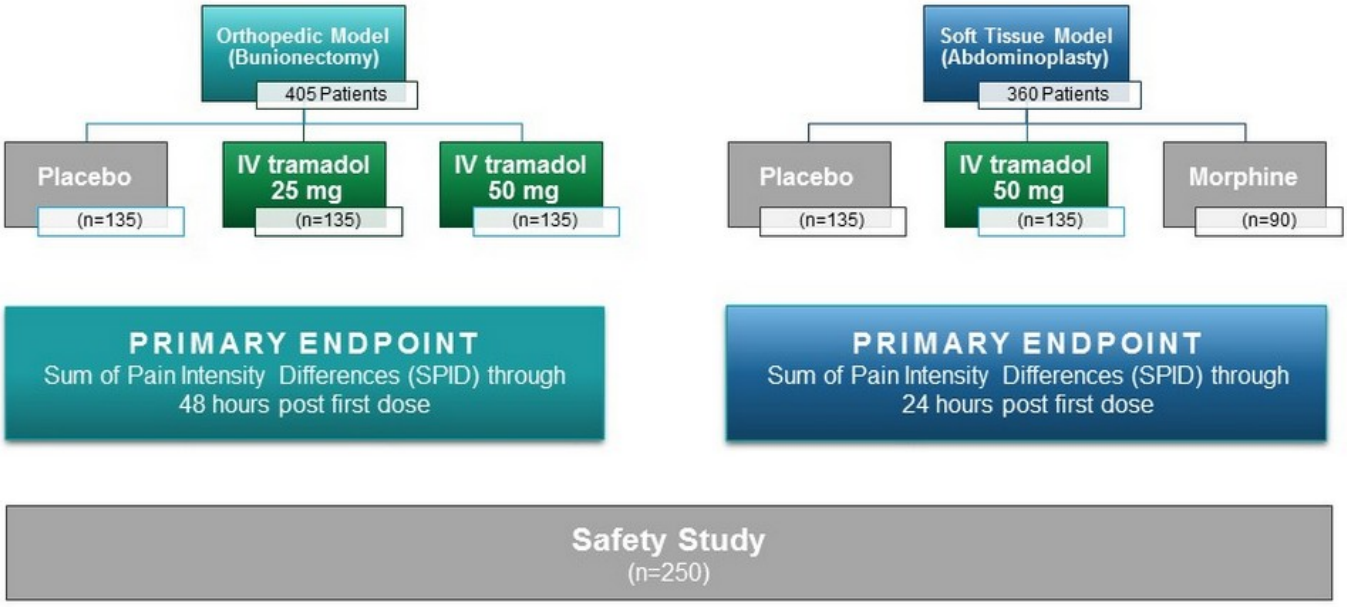
Source: Can Fam Physician. 2010 Jun; 56(6): 514–517; Avenue research

Unique Dual Mechanism of Action Among IV Analgesics



Schedule IV versus Conventional Narcotics (Schedule II)

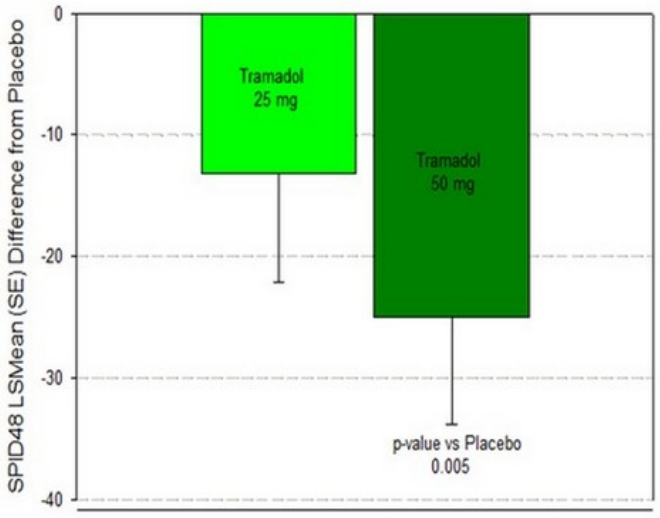
Phase 3 Program Overview



Bunionectomy Study Results

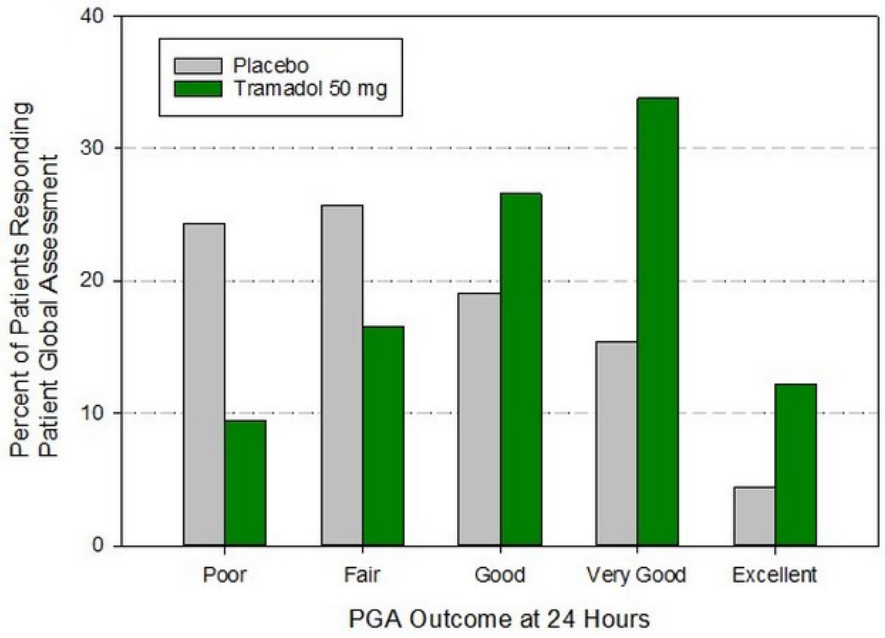
IV Tramadol 50 mg Achieves Primary Endpoint and All Key Secondary Endpoints

- P=0.005 for the primary endpoint of SPID48 (Sum of Pain Intensity Difference over 48 hours)
- Key secondary endpoints included:
  - SPID24
  - Total consumption of rescue medicine
  - Patient Global Assessment, captures patients' perception of treatment
- Rapid onset of efficacy
  - Statistically significant pain reduction seen as early as 30 minutes after dosing



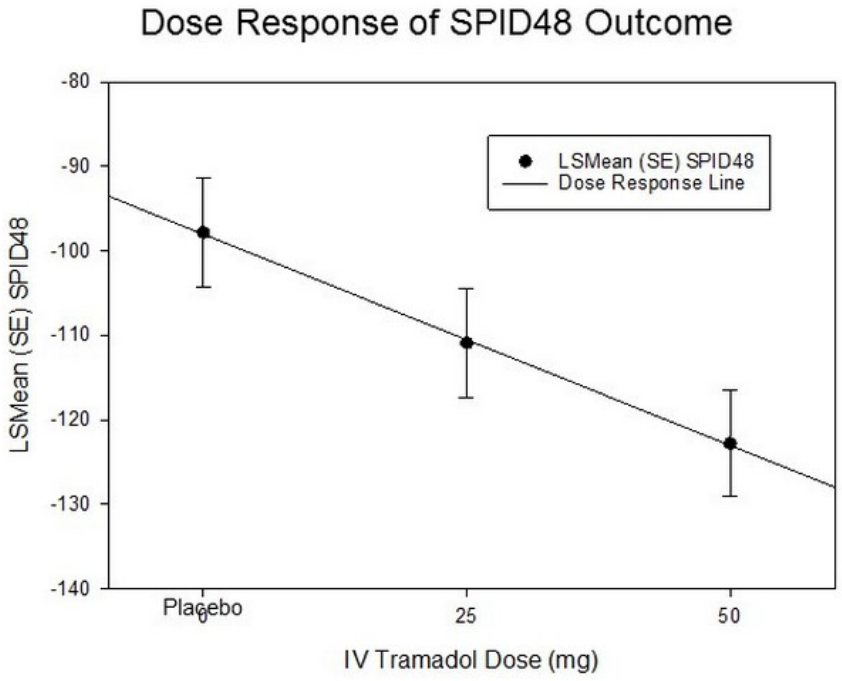
Favorable Patient Reported Outcome

The Patient Global Assessment (PGA), which captures patients' perception of the treatment, demonstrated statistically significant improvement over placebo.



Statistically Significant Dose Response

A clear dose response confirms that the 50 mg dose will move forward.



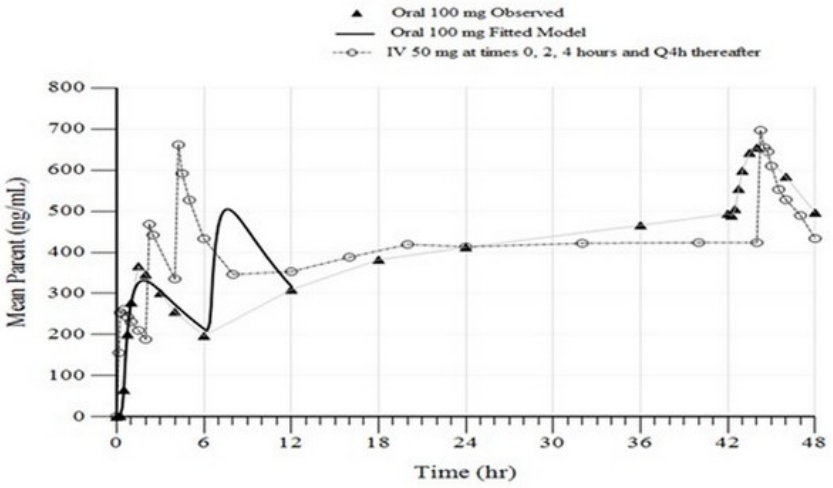
No Surprise in Safety Outcomes

IV Tramadol 50 mg Was Well Tolerated

- There were no drug-related serious adverse events (SAEs)
- The most common (≥5%) adverse events in the trial where IV tramadol 50 mg differed from placebo were nausea, vomiting, dizziness and somnolence.
  - Most of these adverse events were mild or moderate (Grade 1 or 2) with only 4 (3%) patients experiencing a Grade 3 event (vomiting) and no Grade 4 events in the IV tramadol 50 mg group
  - One patient in the 50 mg IV tramadol arm discontinued from the study due to adverse events.
- IV Tramadol 50 mg patients were able to complete the study and receive all their treatment doses
  - Only 2 (1.4%) IV Tramadol 50 mg patients discontinued the study, versus 16 (11.8%) placebo patients
  - 98.6% of IV Tramadol 50 mg patients received their full course of infusions during the study

Novel Dosing Regimen Maximizes Efficacy and Tolerability

- IV tramadol 50 mg is infused intravenously over 15 minutes at Hours 0, 2, 4, and once every 4 hours thereafter
- Similar C_{max} and AUC to that of 100 mg oral tramadol given every 6 hours at steady state



Post-Surgical Pain Management is a Gateway to Opioid Dependence

Approximately 6% of patients become new persistent opioid users in the post-surgical setting

"In this population-based study of 36,177 surgical patients, the incidence of new persistent opioid use after surgical procedures was 5.9% to 6.5% and did not differ between major and minor surgical procedures."[1]

Regimens initiated with conventional narcotics have a significant association with opioid misuse

"After adjusting for covariates, other risk factors… including benzodiazepines …as well as regimens initiated with hydromorphone… and oxycodone …had a statistically significant association with opioid misuse."[2]

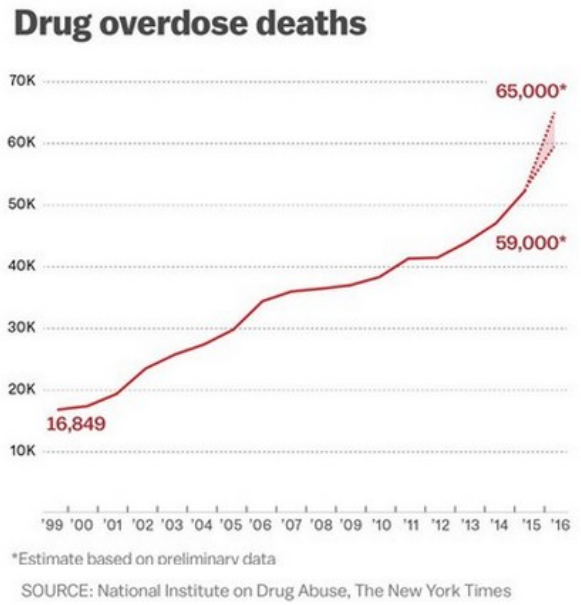
(1) Brummett CM, Waljee JF, Goesling J, et al. New Persistent Opioid Use After Minor and Major Surgical Procedures in US Adults. JAMA Surg. 2017;152(6):e170504.

(2) Brat GA, Agniel D, Beam A, et al. Postsurgical prescriptions for opioid naïve patients and association with overdose and misuse: retrospective cohort study. BMJ. 2018:Jan 17;360:j5790.

Opioid Crisis Puts Pressure on the Use of Conventional Narcotics

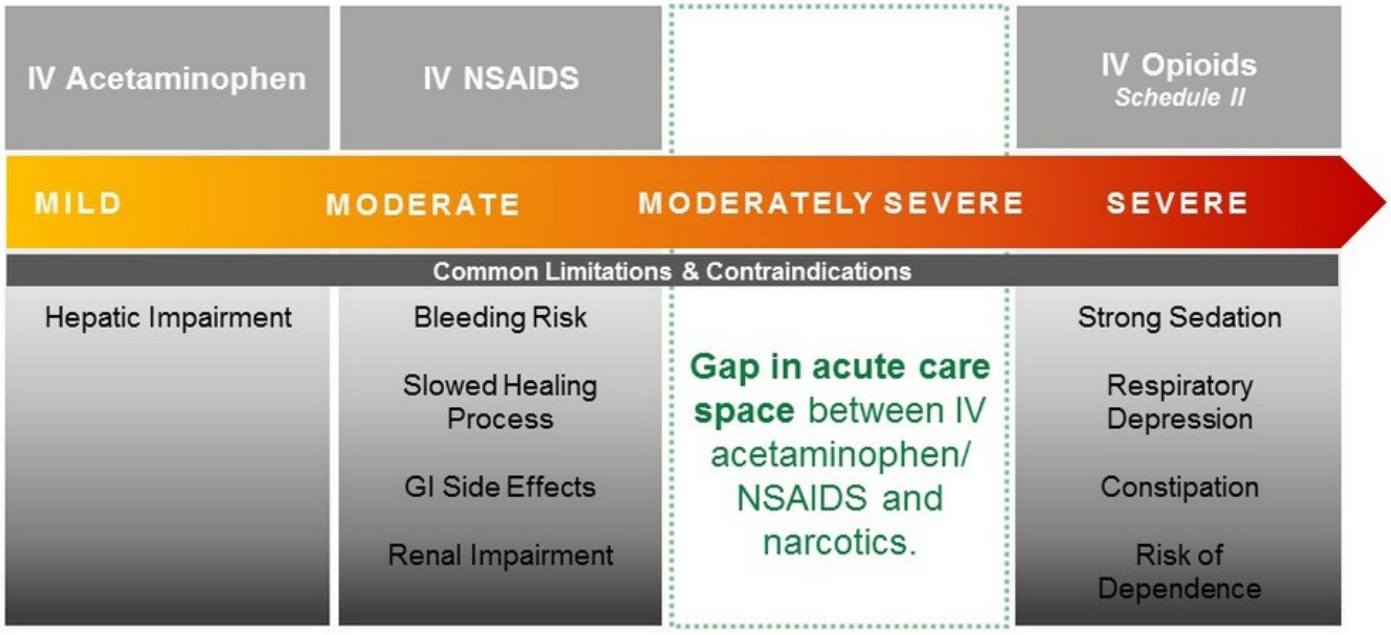
"IV to Oral" Tramadol is Positioned to Help Reduce Conventional Opioid Usage in the Postoperative Setting

- **Release of the CDC guidelines:**
  - *"When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed."*
- **DEA has proposed a 20% reduction** in the manufacture of opioids for 2018
- **CVS/other pharmacies limiting opioid (new) prescriptions** to 7 days and the daily dosage (mg)



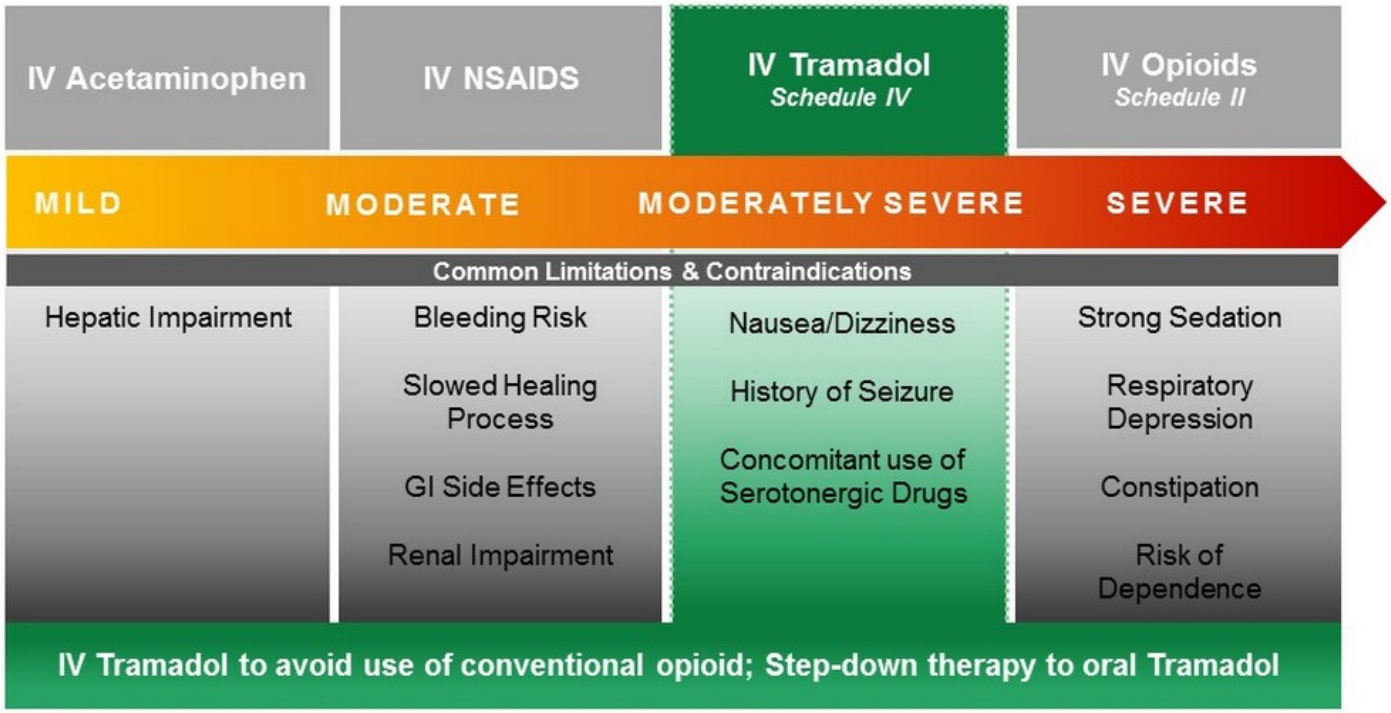
What is the Unmet Need in Post-op Pain Care?

Current Post-Op Pain Management Paradigm

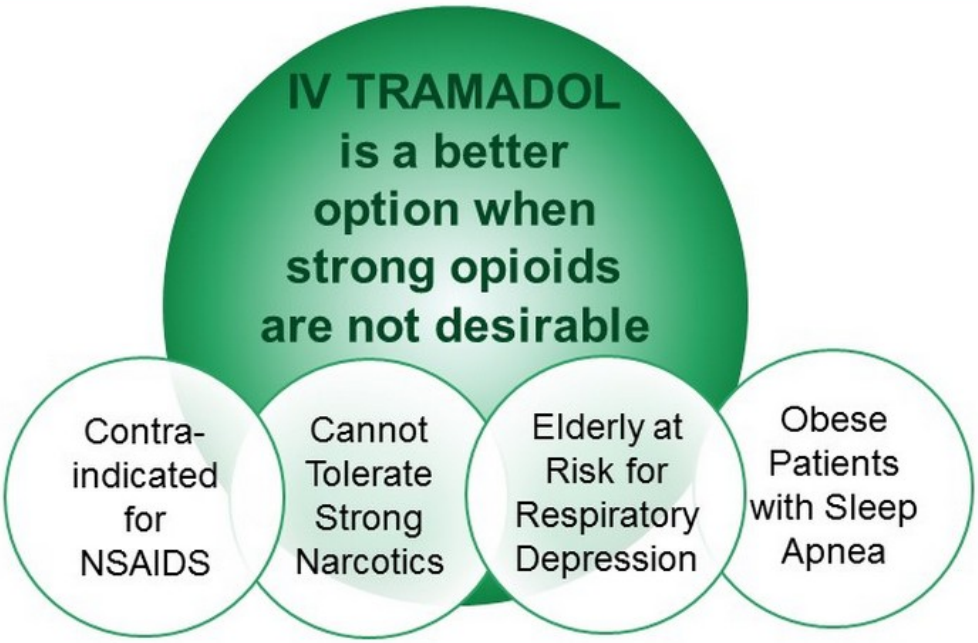


IV Tramadol Ideally Suited for Wide Range of Patients

Future Post-Op Pain Management Paradigm



Many Patients Could Benefit from IV Tramadol



For the other patients: Why use a conventional (Schedule II) opioid when IV tramadol might be adequate for pain control?

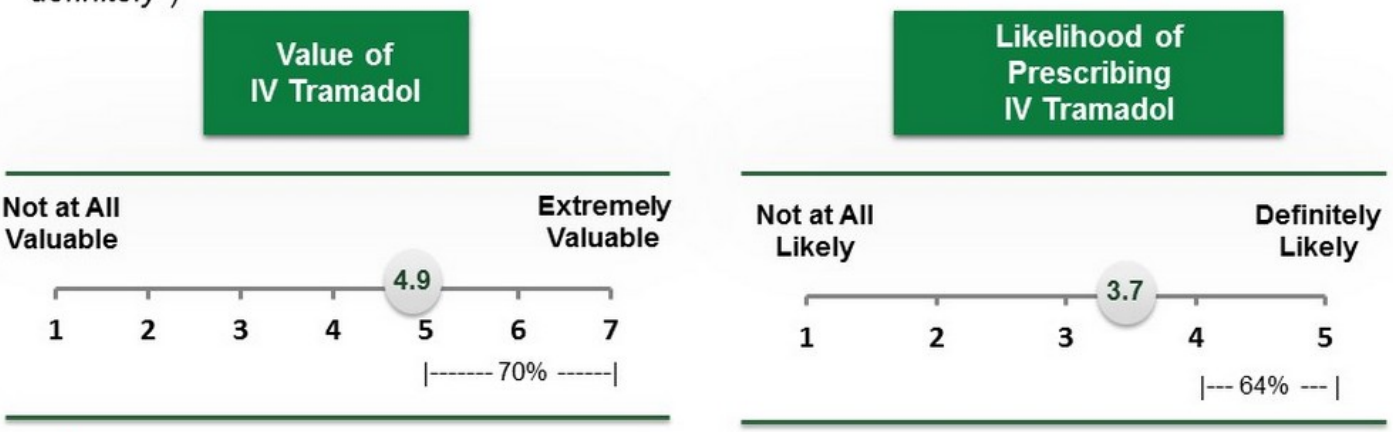
Physician Excitement for IV Tramadol Product Profile

Surgeons valued the potential benefits of IV Tramadol as an important addition to the IV analgesic armamentarium, assigning IV Tramadol a mean rating of 4.9

- 80% of orthopedic surgeons and 76% of general surgeons rated IV Tramadol "*5 or higher*" on a 1-7 rating scale

The majority of practitioners expressed a strong interest in prescribing IV Tramadol

- Almost two-thirds (64%) were "*probably-definitely*" likely to prescribe; surgeons, in particular, orthopedic surgeons, displayed the highest prescribing intent (74% - "*probably-definitely*")

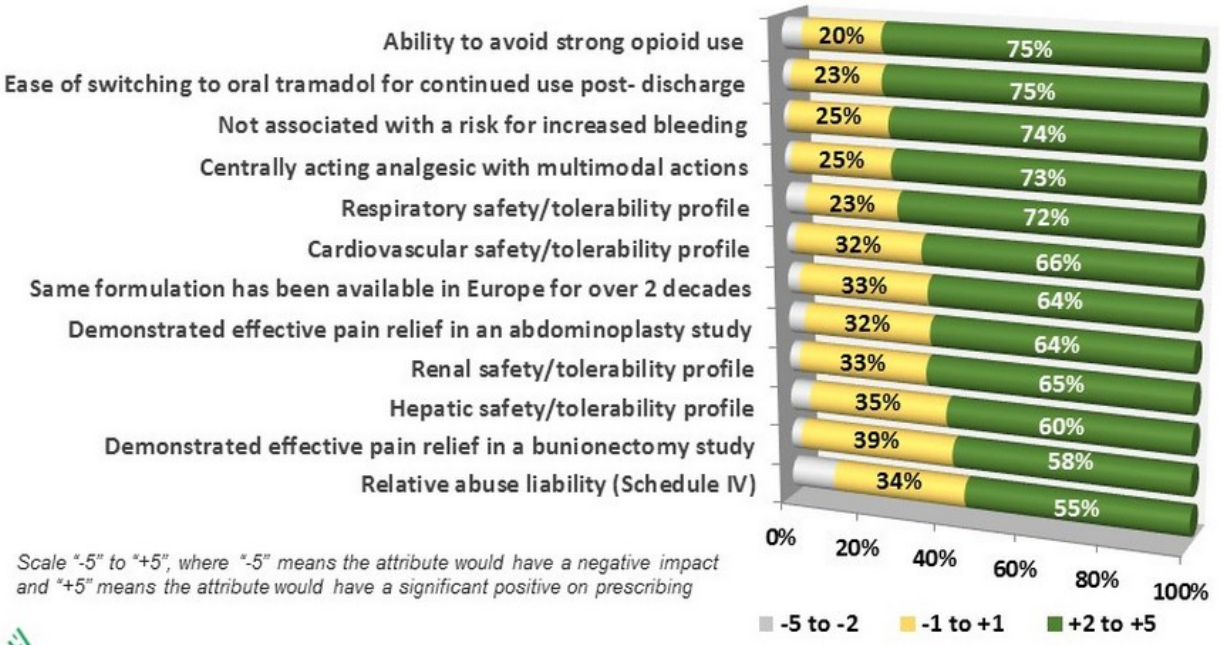


Characterizing the Acceptance of IV Tramadol in the Treatment of Acute (post-surgical) Pain. Internet survey - n=201 practitioners (orthopedic surgeons; general surgeons, anesthesiologists; and emergency medicine physicians)

Characteristics Supportive of IV Tramadol Usage

The potential for IV Tramadol to offer an alternative to use of strong opioids was viewed as the most significant enticement to prescribe

- A direct transition from an IV to oral formulation and potential safety benefits vs. both opioids and non-opioids would also be very meaningful to clinicians



Scale "-5" to "+5", where "-5" means the attribute would have a negative impact and "+5" means the attribute would have a significant positive on prescribing

Characterizing the Acceptance of IV Tramadol in the Treatment of Acute (post-surgical) Pain. Internet survey - n=201 practitioners (orthopedic surgeons; general surgeons, anesthesiologists; and emergency medicine physicians)

Strong Patent Portfolio

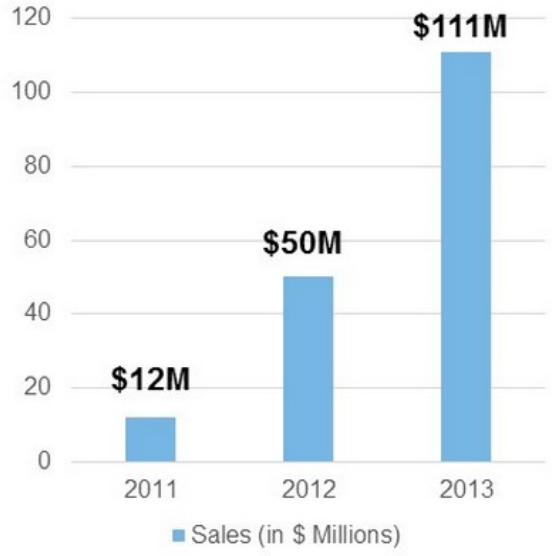
- U.S. Patents No. 8,895,622, No. 9,561,195, No. 9,566,253, No. 9,962,343
  - Expire in 2032
- U.S. Patents No. 9,693,949, No. 9,968,551, No. 9,980,900
  - Expire in 2036
- Potential for Additional Patents

A Prior Success Story – IV Acetaminophen

Cadence Pharmaceuticals - OFIRMEV ®

- Licensed drug from Bristol-Myers Squibb in 2006 – upfront fee of $25 million and $15 million milestone upon FDA approval
- FDA approval in November 2010 and launched in January 2011
- List price of $14.75 per vial as of 2013
- Royalties in mid-teens to mid-twenties
- Acquired on February 11, 2014 for $1.3 billion by Mallinckrodt
- Expected authorized generic launch in December 2020

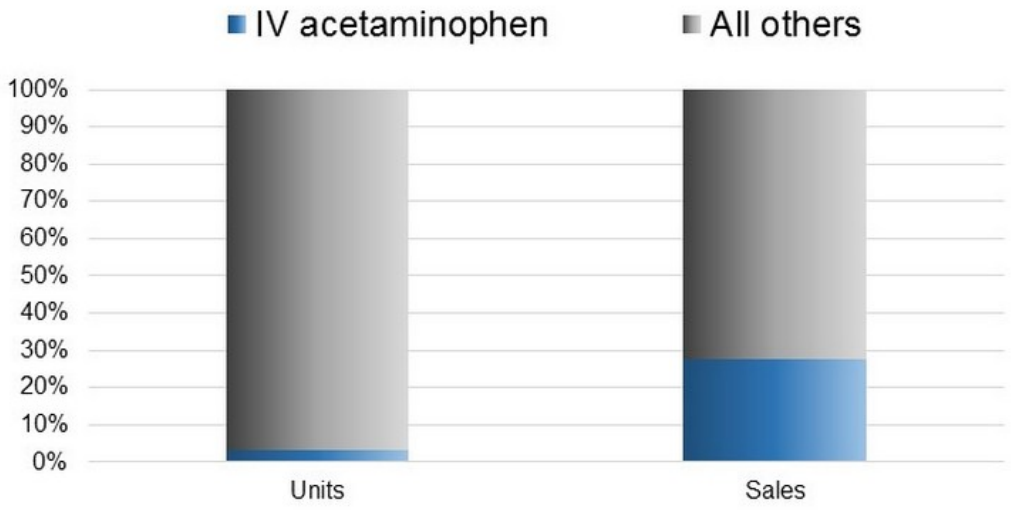
Sales:



Key Analogue for IV Tramadol

Revenues for Ofirmev® (IV acetaminophen) are ~$300 MM per year

Ofirmev® accounts for ~30% of the total dollar market on approximately 3 to 4% of the unit volume



Financial Highlights

Market capitalization	~$40 million
Outstanding shares (As of 3/31/18)	10.6 million
Cash position (As of 3/31/18)	$15.0 million

Upcoming Milestones

Initiated Phase III bunionectomy study	3Q 2017	✓
Initiated Safety study	4Q 2017	✓
Positive topline data from Phase III bunionectomy study	2Q 2018	✓
Initiate Phase III abdominoplasty study	3Q 2018	
Topline data from Phase III abdominoplasty study	2Q 2019	
Complete Safety study	2Q 2019	
Submit NDA	Year-end 2019	

AVENUE THERAPEUTICS, INC. | NASDAQ: ATXI | MAY 2018