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CAPSTONE THERAPEUTICS CORP.

FORM 8-K
(Current report filing)

Filed 02/11/16 for the Period Ending 02/11/16

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Telephone	6022865520
CIK	0000887151
Symbol	CAPS
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

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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: February 11, 2016 (Date of earliest event reported)

CAPSTONE THERAPEUTICS CORP.
(Exact name of registrant as specified in its charter)

Delaware	000-21214	86-0585310
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

1275 West Washington Street, Suite 104, Tempe, Arizona	85281
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code:
(602) 286-5520

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 (see General Instruction A.2. below):

[ ] 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))

Section 2—Financial Information

Item 2.02 Results of Operations and Financial Condition.

A copy of the presentation for the conference call, referenced in the press release issued by Capstone Therapeutics Corp. on February 3, 2016, is furnished as Exhibit 99.1 to this Current Report on Form 8-K, entitled "Capstone Therapeutics Corp. Operating Update, February 11, 2016". The presentation will also be accessible during the conference call by logging onto the Investors section of the Company's website, www.capstonethx.com.

The information in Item 2.02 of this Form 8-K and Exhibit 99.1 furnished herewith shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities under that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in any such filing.

Section 9 – Financial Statements and Exhibits

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Capstone Therapeutics Corp. Operating Update, February 11, 2016

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.

Dated: February 11, 2016

CAPSTONE THERAPEUTICS CORP.

/s/ John M. Holliman, III
John M. Holliman, III
Executive Chairman

Capstone Therapeutics (OTCQB: CAPS)

Operating Update

February 11, 2016

4:30 p.m. EST Conference Call

Safe Harbor Statement

Statements in this presentation or otherwise attributable to Capstone regarding our business that are not historical facts are forward looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from predicted results. These risks include the factors discussed in our Form 10-K for the fiscal year ended December 31, 2014, and other documents we file with the U.S. Securities and Exchange Commission.

LipimetiX Development, Inc., is 60% owned by Capstone Therapeutics Corp. (OTCQB: CAPS).

JV Milestones Over Last 15 Months

I. **Reported Phase 1a/1b/2a Human Clinical Studies (51 Subjects)**
   - Met All Study Objectives
   - Powerful and Rapid Reduction in VLDL and Triglycerides

II. **Discovered Next Gen Apo E mimetics (AEM 28-14)**
   - 4X More Efficacious than parent peptide
   - New composition of matter patent application
     - Potential 21 Year Fresh Patent Life

III. **New Formulation**
   - Better Tolerated
     - 5X increased in NOAEL dose
     - GRAS excipients – easy to manufacture

IV. **Potential SubQ Administration Opens Large Chronic and Orphan Indications**
   - Diabetic dyslipidemia
   - Refractory hypertriglyceridemias

Targeting Next Stage of Program Development

Fundraising Chronology

June 2015	Announced Dismissal of 6 Year Qui Tam Lawsuit
June 2015	Filed S-1 Registration Statement for $10MM
Sept 2015	Investment Bank Receives FINRA Allowance for CAPS Engagement
Sept/Oct 2015	Marketing Meeting / Travel
Nov 2015	Verbal Agreement with CAPS Shareholder to Purchase Exclusive Period (Due Diligence) for Right to Invest Up to $10MM
Dec 2015	Closed $1MM Secured Loan Under Signed Securities Purchase Agreement with CAPS Shareholder; 8-K Filed
Jan 13, 2016	In-Person Meeting with CAPS Shareholder
Jan 29, 2016	CAPS Shareholder Notifies Decline of Additional Investment Due To Changing Market Conditions / Exclusive Period Ends
Feb 3, 2016	CAPS 8-K Filings: (1) End of Exclusive Period and (2) Material Transfer Agreement with a Pharma

AEM-28-14 Program Requires Capital To Achieve Development Milestones

CAPS Shareholder Value Preservation Plan

Capstone Assets:

- Cash and receivables
- 60% Ownership in LipimetiX Development, Inc.
  (AEM-28-14 Program in HoFH, Hypertriglyceridemia, Diabetic Dyslipidemia)

Premise:

- LipimetiX stock may have significant future value
- Protect and preserve that potential value for benefit of CAPS Shareholders

Action Plan:

- Target 12+ months of Capstone operations by further reducing budget – LipimetiX needs capital to operate
  - Slash already low cash burn rate / employee compensation
  - Cease full-compliance SEC reporting as of 3/31/2016
  - Continue to file 10-K's, 10-Q's and 8-K's (without audit)
  - Listing fee paid
  - All shareholder info posted on www.capstonethx.com

CAPS Shareholder Value Preservation Plan (Continued)

Future Funding:

- Stock price is so low that any fundraising in CAPS is extremely dilutive to SH – turbulence in stock market
  - Fundraising in CAPS de-emphasized
  - Pulled S-1 Filing

- Raise New Funds in LipimetiX
  - LipimetiX raise is likely at higher valuation than CAPS' depressed market cap
  - Fund AEM-28-14 Program to value inflection points
  - Engage with pharma partners to accelerate potential liquidity event (option or license)

LipimetiX Has Initiated Private Equity Raise Process

AEM-28-14 Program Update

New Chimeric Peptides: AEM-28 Analogs: AEM-28-14

- **Program will advance newly-discovered AEM-28-14 which has been developed by LipimetiX /University of Alabama**

- **New IP**
  - AEM-28 analogs composition of matter (CoM) patent application filed July 2014.
  - Patent application specifying AEM-28-14 converted to full US and PCT July 2015.
  - New formulation patent application filed January 2016.

- **Enhanced efficacy**
  - AEM-28-14 4X more efficacious than AEM-28 in mouse models.
  - Binds and clears all classes of lipoproteins

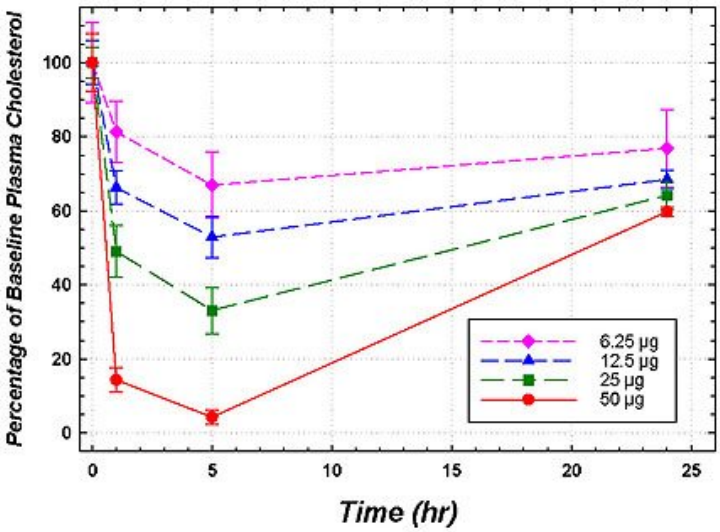
- **Improved safety and toleration**
  - Mechanism of venous irritation identified
  - Novel formulation prevents peptide aggregation
  - Greater than 5X increase NOAEL dose in mouse models.
  - GRAS excipients, easy to manufacture

- **Combination of enhanced efficacy and safety may yield 20X increase in therapeutic window over original AEM-28.**

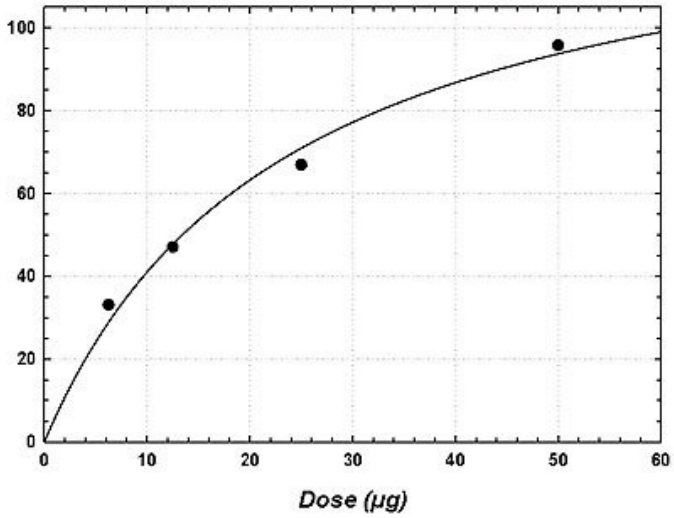
Potential 21 Year Patent Life Extends Commercial Value /
Potential 20X Increase in Therapeutic Window

AEM-28-14: Preclinical Efficacy

Comparison of Efficacy of Varying Doses of AEM-28-14 for Reducing Cholesterol in Apo E Null Mice (± SEM)

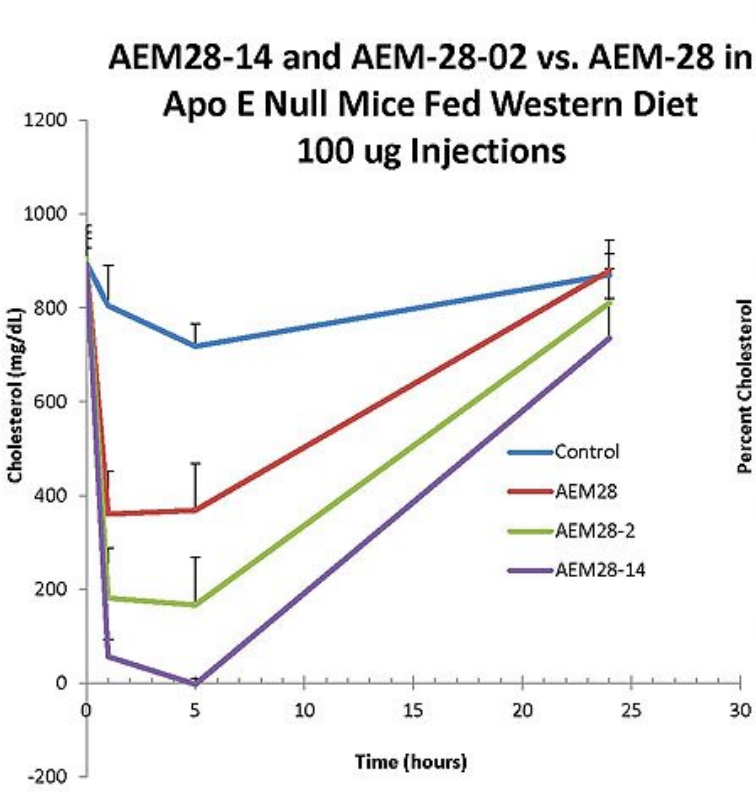


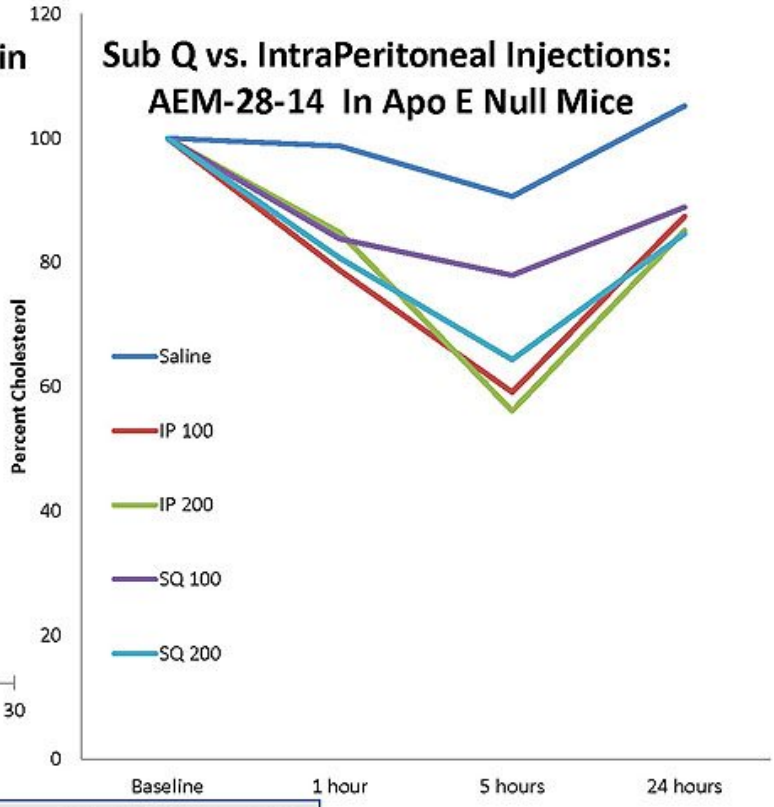
Dose vs Maximum Percent Decrease in Plasma Cholesterol with AEM-28-14 in Apo E Null Mice (Hyperbolic Curve Fit)



From Baseline of 480 mg/dL, AEM-28-14 Virtually Eliminates Plasma Cholesterol in this Murine Model

Efficacy Data with new Chimeric Peptides





AEM-28-14: Remarkable Efficacy and SubQ Potential

AEM-28-14 Development Plan
What Does Pharma Want To See?

1) Full Pre-IND Tox/PK Package
2) Full CMC Package
3) Phase 1a – Single Ascending Dose – Safety/Efficacy
4) Phase 1b – Multiple Ascending Dose – Safety/Efficacy
5) Phase 2
   - Multi-center, Multi-dose in Subjects with Refractory Hypertriglyceridemia
   - Type 4 and 5 Refractory TG Patients
   - Chronic, Recurring Acute Pancreatitis Patients with High Residual TGs
   - Diabetes 2 and Metabolic Syndrome Patients

Business Goal: Show Pharma <u>Unprecedented</u> Efficacy in TG Reduction

Company Estimated AEM-28-14 Development Schedule

Estimate of 26 Months from Pre-Clinical to Phase 2 Data:
LipimetiX Delivered Prior AEM-28 Phase 2a Data on Time and On Budget

AEM-28-14 Development Plan

Plan Is To "Partner" Phase 2b/3 Trials Which Can Be Targeted To Multiple TG/Cholesterol Indications:

- **Orphan Indications – fastest route to market**
  - Hypertriglyceridemic Acute Pancreatitis
  - HoFH
- **Atherosclerotic Vascular Diseases – large markets, short treatment**
  - Diabetic / Vascular Complications
  - Acute Coronary Syndrome
- **Dyslipidemia – large markets, extended treatment**
  - Metabolic Syndrome
  - Severe Refractory Hypertriglyceridemia

Large, Valuable Target Markets / Broad Indication Appeal to Potential Pharma Partners

Summary

- **PRESENT FOCUS WILL BE RAISING NEW CAPITAL IN LIPIMETIX**
- **LIPIMETIX IS ACTIVELY INVOLVED IN THE PROCESS OF RAISING CAPITAL NOW (AMOUNT AND VALUATION TO BE DETERMINED BY MARKET)**
- **AEM-28-14 Program**
  - Composition of Matter IP Through 2035
  - Unprecedented Efficacy / Increased Tolerability
  - Subcutaneous Delivery Potential
  - Relatively Low Cost Program to Human Data
  - Molecule Now Being Evaluated By Potential Pharma Partner

Risk-Mitigated LipimetiX AEM-28-14 Program Targeting Valuable Pharma Markets

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