
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 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): September 26, 2017

Sucampo Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-33609
(Commission File Number)

30-0520478
(IRS Employer
Identification No.)

**805 King Farm Blvd, Suite 550
Rockville, Maryland 20850**
(Address of principal executive offices, including zip code)

(301) 961-3400
(Registrant's telephone number, including area code)

N/A
(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). 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

On September 26, 2017, Sucampo Pharmaceuticals, Inc. (“Company”) will make a corporate update presentation at the 2017 Cantor Fitzgerald Global Healthcare Conference, as well as during one-on-one meetings with analysts and investors. All meetings will include written communication comprised of slides. The slides from the presentation are being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in the presentation furnished as Exhibit 99.1 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and is not incorporated by reference into any of the Company’s filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as shall be expressly set forth by specific reference in any such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

[99.1 Presentation entitled “Sucampo Pharmaceuticals, Inc. – Emerging Specialized Disease Company”, dated September 26, 2017.](#)

SIGNATURE

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.

SUCAMPO PHARMACEUTICALS, INC.

Date: September 26, 2017

By: /s/ Alex Driggs

Name: Alex Driggs

Title: General Counsel & Corporate Secretary



Sucampo Pharmaceuticals, Inc.

Emerging Specialized Disease
Company

Cantor Fitzgerald Global
Healthcare Conference
September 26, 2017



Forward Looking Statement

This presentation contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management's current expectations and involve risks and uncertainties, which may cause results to differ materially from those set forth in the statements. The forward-looking statements may include statements regarding product development, and other statements that are not historical facts. The following factors, among others, could cause actual results to differ from those set forth in the forward-looking statements: the impact of pharmaceutical industry regulation and health care legislation; Sucampo's ability to accurately predict future market conditions; dependence on the effectiveness of Sucampo's patents and other protections for innovative products; the effects of competitive products on Sucampo's products; and the exposure to litigation and/or regulatory actions.

No forward-looking statement can be guaranteed and actual results may differ materially from those projected. Sucampo undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise. Forward-looking statements in this presentation should be evaluated together with the many uncertainties that affect Sucampo's business, particularly those mentioned in the risk factors and cautionary statements in Sucampo's most recent Form 10-K as filed with the Securities and Exchange Commission on March 8, 2017, as amended, as well as its filings with the Securities and Exchange Commission on Forms 8-K and 10-Q since the filing of the Form 10-K, all of which Sucampo incorporates by reference.

Non-GAAP Metrics

This presentation contains three financial metrics (**Adjusted Net Income, EBITDA, Adjusted EBITDA, and free cash flow**) that are considered "non-GAAP" financial metrics under applicable Securities and Exchange Commission rules and regulations. These non-GAAP financial metrics should be considered supplemental to and not a substitute for financial information prepared in accordance with generally accepted accounting principles. The company's definition of these non-GAAP metrics may differ from similarly titled metrics used by others. Adjusted Net Income adjusts for specified items that can be highly variable or difficult to predict, and various non-cash items, which includes amortization of acquired intangibles, inventory step-up adjustment, R&D intangible asset impairment, one-time severance payments, restructuring costs, acquisition related expenses, amortization of debt financing costs, debt extinguishment, R&D license option expense, foreign currency translations and the tax impact of these adjustments. EBITDA reflects net income excluding the impact of provision for income taxes, interest expense, interest income, depreciation, R&D intangible asset impairment, amortization of acquired intangibles and inventory step up adjustment. Adjusted EBITDA reflects EBITDA and adjusts for specified items that can be highly variable or difficult to predict, and various non-cash items, which includes share based compensation expense, restructuring costs, one time severance payments, acquisition related expenses, debt extinguishment, R&D license option, and foreign currency translations. Free cash flow reflects net cash provided by operating activities less expenditures made for property and equipment. The company views these non-GAAP financial metrics as a means to facilitate management's financial and operational decision-making, including evaluation of the company's historical operating results and comparison to competitors' operating results. These non-GAAP financial metrics reflect an additional way of viewing aspects of the company's operations that, when viewed with GAAP results may provide a more complete understanding of factors and trends affecting the company's business.

The determination of the amounts that are excluded from these non-GAAP financial metrics is a matter of management judgment and depends upon, among other factors, the nature of the underlying expense or income amounts. Because non-GAAP financial metrics exclude the effect of items that will increase or decrease the company's reported results of operations, management strongly encourages investors to review the company's consolidated financial statements and publicly-filed reports in their entirety.



Investment Highlights

- Global biopharmaceutical company focused on specialty areas with high unmet medical needs
- Late stage pipeline with 3 phase 3 programs with data readouts over next 12-24 months
 - VTS-270 for Niemann-Pick Disease Type C1 (NPC) from recent acquisition of Vtesse Inc.
 - CPP-1X/sul combo in Familial Adenomatous Polyposis (FAP)
 - Life-cycle management programs for lubiprostone
- Two marketed and outlicensed products in gastroenterology and ophthalmology providing >\$200 million in annual revenue and significant operating cash flow to fund pipeline and operations and limit downside risk
 - AMITIZA for constipation
 - RESCULA in ophthalmology
- Focused business development strategy focused on capital efficient, highly specialized diseases to bolster growth and diversify
- Deep management team with proven ability to transform the company, create value, and commercialize products

Diversified and Late Stage Portfolio

| Product | Indication | Phase 3 | Registration |
|------------------|-----------------------------------|---------|--------------|
| VTS-270 | NPC | | |
| CPP-1X/sul Combo | FAP | | |
| Lubiprostone | Pediatric Constipation 6-17 yrs | | |
| | Pediatric Constipation 6mos-6 yrs | | |

NPC-1: Ultra-Rare, Fatal Pediatric Disease with Urgent Patient Need

- NPC-1 is an ultra-rare, progressive and fatal disease caused by defects in lipid transformation within the cell
- Diagnosis of NPC-1 most common outside infantile ages
 - Progressive and irreversible neurological manifestations
 - Estimated 2,000-3,000 cases globally
 - Under- and mis-diagnosed
- NPC-1 results in early death
- Currently no approved treatments for the disease in the U.S.
- VTS-270 has breakthrough therapy designation in the U.S.
- Highly motivated and involved patients, families and physicians with strong commitment to development



VTS-270 for Treatment of NPC-1

- VTS-270 is a highly-purified mixture of 2-hydroxypropyl- β -cyclodextrins with a specific compositional fingerprint that targets cholesterol and sphingolipid storage
- Initially evaluated by consortium of academic labs led by NIH in collaboration with parent and patient advocacy groups
- In preclinical studies, VTS-270 had a profound effect on depleting intracellular cholesterol stores and lysosomal accumulation
- In multiple preclinical animal models of NPC-1, VTS-270 has also shown results in preventing dysfunctions such as ataxia and profoundly impacting survival

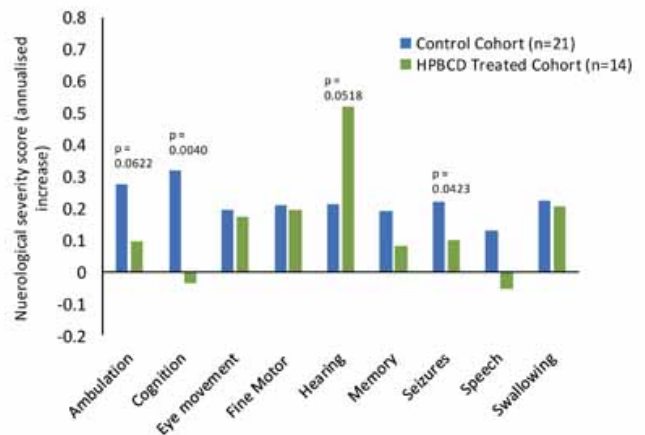
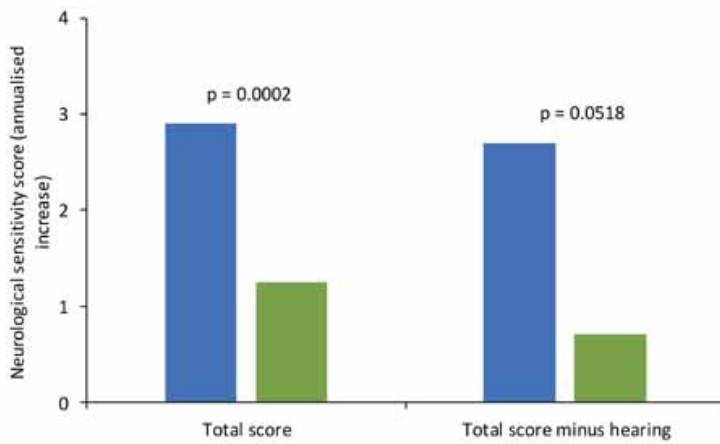


On-going
formulation studies
may culminate in
new intellectual
property for
VTS-270



Clinical Data Phase 1/2 Study

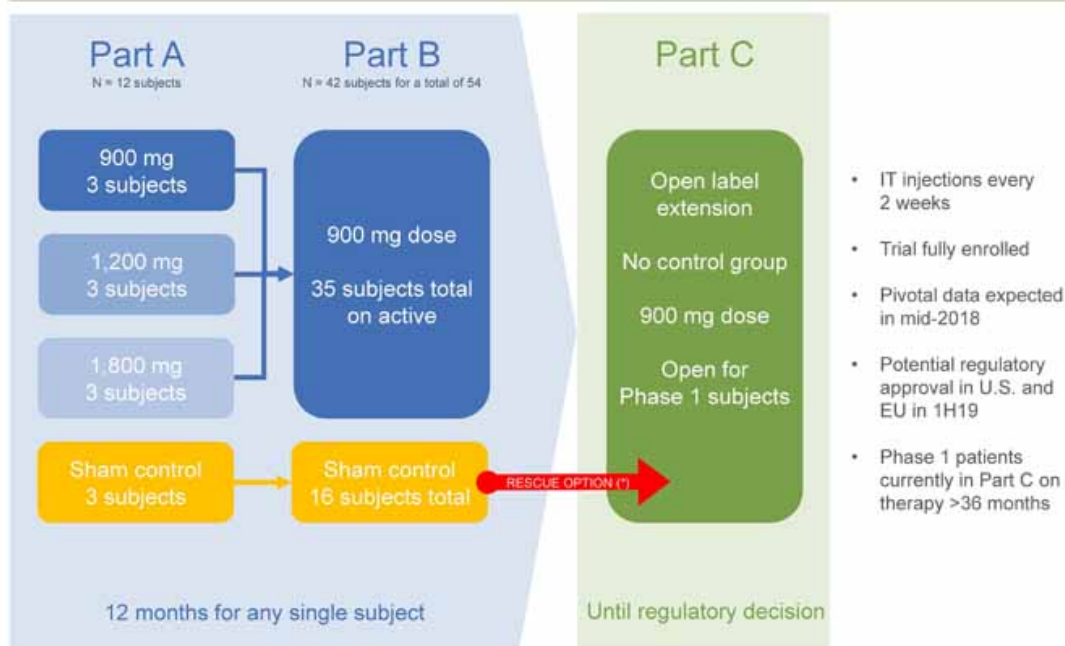
18 Month Treatment Results Reveal that VTS-270 Shows Robust Disease Modification with Durable Effects Over 18 Months



Data published in *The Lancet* August, 2017



VTS-270 Pivotal Trial



Phase 3 Study Endpoints

1. Composite score evaluating the progression of the neurological manifestations in NPC-SS four major domains: ambulation, fine motor, cognition, and swallowing
2. Physician global score: Clinical Global Impression of Change
3. Long-term safety and tolerability of the drug administered by lumbar punctures every 2 weeks

Familial Adenomatous Polyposis (F.A.P.)

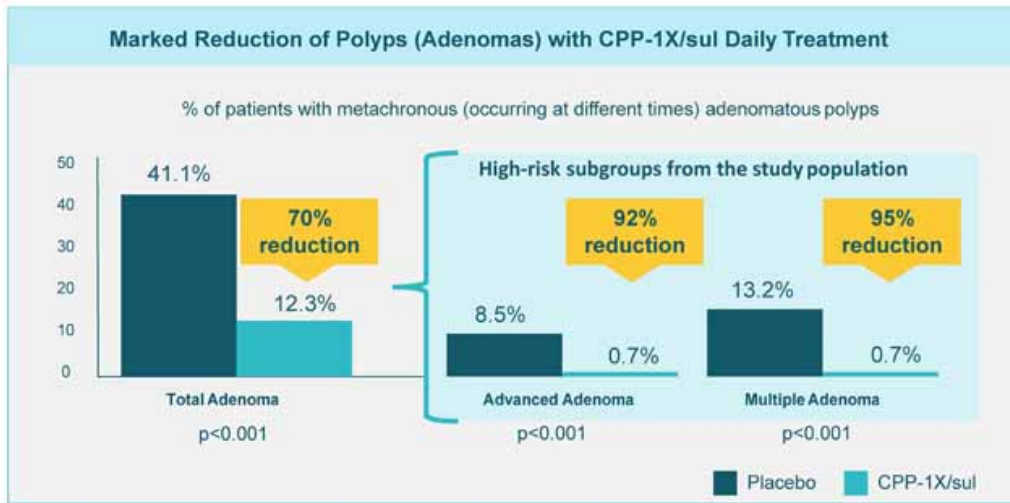
- Significant opportunity
 - Orphan indication in U.S. for familial adenomatous polyposis (FAP)
 - ~30K cases currently
 - No approved treatment options and dire patient need
 - 100% risk of colon cancer
 - Progressive removal of colon/rectum
 - Incremental opportunity of ~\$200M–\$400M
- Additional opportunity in sporadic colon adenoma therapy (CAT)



CPP-1X/Sul Combination

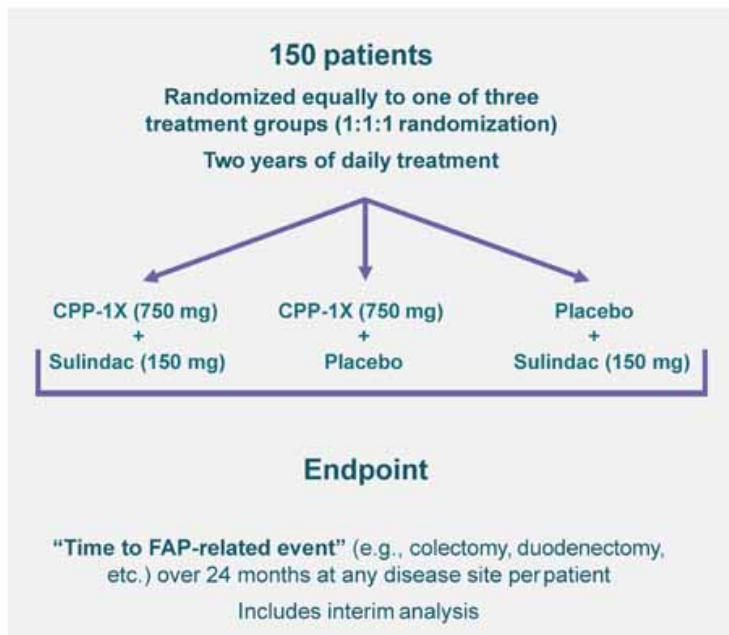
- Exclusive option with Cancer Prevention Pharma for N. America
- Strong scientific rationale
 - CPP-1X decreases polyamine synthesis by blocking Ornithine Decarboxylase (ODC1)
 - Sul (sulindac) increases polyamine catabolism and export by up-regulating transport genes (PPAR γ and SAT)
- Phase 2 proof of concept data in sporadic colon adenoma/FAP
- No statistically significant serious adverse events in Phase 2/3 “Meyskens” trial with 375 patients and three years of daily dosing of CPP-1X/sul
 - Sulindac approved for arthritis and used extensively for many years
- Defined regulatory pathway
- Granted Fast Track status by FDA

Phase 2/3 Meyskens Trial in High-Risk Polyp Formers



Meyskens, et al. CAPR 2008, 1:32-28.

CPP-1X/sul Combination Phase 3 Trial

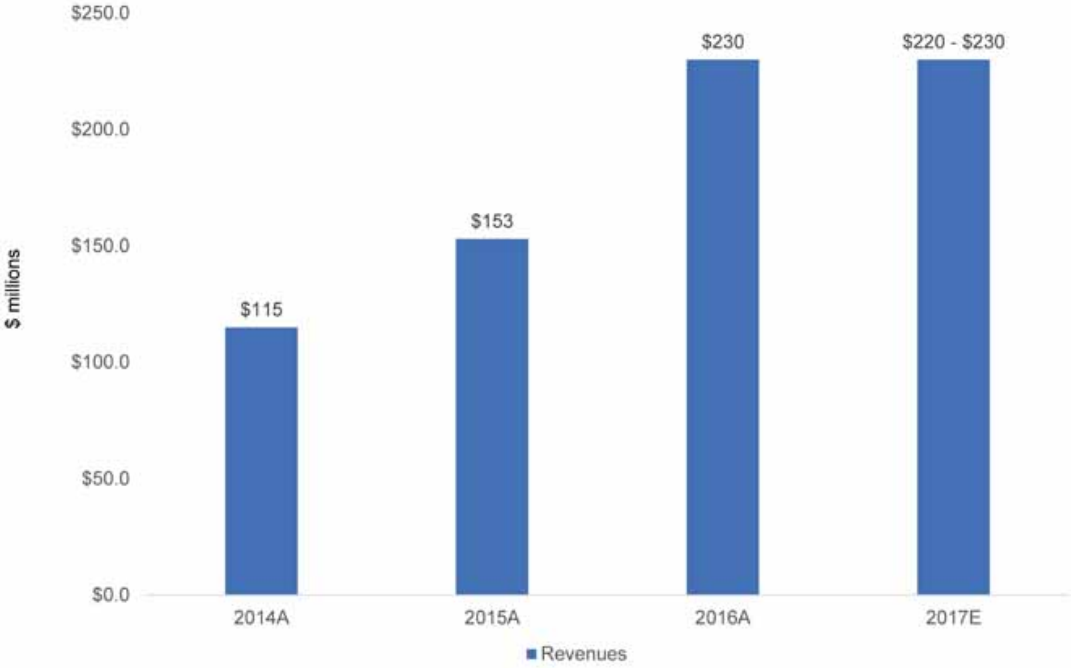


- Fully enrolled, registration eligible study
- 150-patient, three-arm, double-blind randomized trial of the combination agent and the single agent comparators
- Passed futility analysis in 1H 2017
- Expected to conclude in 2018, with potential approval in 2019

Marketed Products Licensed to Pharma Partners

| Product | Partner | Region |
|---------|---------------|-----------------------|
| AMITIZA | Takeda | North America and ROW |
| | Mylan | Japan |
| | Harbin Gloria | China |
| RESCULA | Santen | Japan |

Marketed Products De-risk, Fund Operations & Growth



AMITIZA: Constipation Market Overview

amitiza[®]
lubiprostone

Significant unmet need in efficacy, safety and patient satisfaction

- U.S. constipation market is large and growing: ~\$5B
 - Branded and generic Rx market: \$4B / ~50M scripts/year ⁽¹⁾
 - OTC market: \$800M / 23M units (30-day supply) / year

Opportunity to convert unsatisfied patients from OTC, generic options

- Majority of prescription and OTC treated patients currently not satisfied with treatment
 - 60%+ of patients on OTCs report ineffective relief of multiple symptoms
 - OTCs not indicated for long term/chronic use
- Only 8% of Rx patients are on novel, branded products
 - Low awareness of chronic Rx options

Strategy: Convert from OTC and Generics to AMITIZA

- **Only product approved for all 3 constipation indications (CIC, IBS-C, OIC)**
- **Differentiated MOA: localized CIC-2 activation with dual action**
- **Demonstrated efficacy and tolerability**
 - Most experienced product: 2M patients and 11M+ exposures over 10+ years
 - Well-tolerated product with established safety profile, no black box warning



- **Paragraph IV filing by Teva; Sucampo + Takeda filed lawsuit in NJ District Court**

1) Source: IMS and Wall Street research.

AMITIZA Lifecycle Management and Update on New Formulation

New Pediatric Functional Constipation (PFC) Indication

- U.S. Prevalence: 18% of pediatric population (13.5M)
- Unmet need: No FDA-approved therapies for PFC (black box warning for linaclotide; prucalopride failed in Phase 4); patients use OTC drugs off-label

Phase 3 Program in Children for PFC:

- sNDA filed for PFC for 10-17 years of age, based on efficacy and safety Ph 3 data in this age group
- Will initiate PFC Ph 3 in children 6 mos – 5 years of age pending FDA feedback

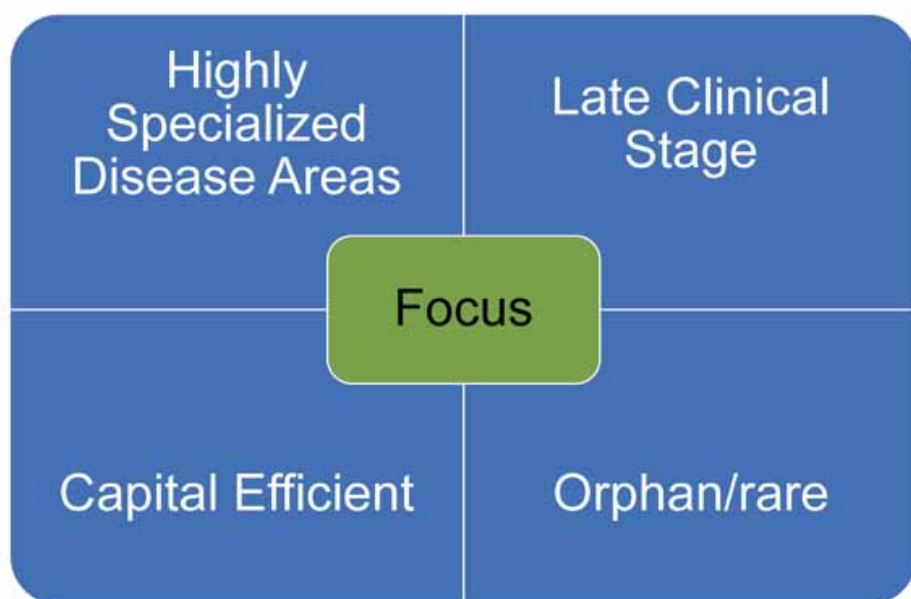
Update on Alternate Sprinkle Lubiprostone Formulation

- Alternate formulation for additional adult and pediatric patients who cannot tolerate capsules, or nasogastric tube-fed patients
- Recent Phase 3 to evaluate bioequivalence of sprinkle and capsule vs. placebo in adults with CIC:
 - Bioequivalence not demonstrated
 - Sprinkle formulation showed statistically significant activity and efficacy vs placebo, and is well-tolerated
 - Will not file NDA for sprinkle formulation in adults

Upcoming Milestones

| Product | Event | Expected Timing |
|--------------------------------|--|---------------------------|
| AMITIZA | Initiation of Phase 3 pivotal PFC, incl. extension option (6 months–5 years) | TBD, pending FDA feedback |
| VTS-270 | Top-line data from Phase 2b/3 pivotal trial in NPC-1 | Mid-18 |
| CPP-1X/sul combination product | Top-line data from Phase 3 pivotal | 2H18 |
| VTS-270 | File NDA for NPC-1 | 2H18 |
| CPP-1X/sul combination product | File NDA for FAP | 2H18 |

Business Development Strategy



Strong Financial Performance for Q2-17

| Summary of Results | Q2 '17 GAAP | Q2 '17 Adj | % Increase Q2'17 vs Q1'17 Adj |
|--------------------|----------------|---------------|-------------------------------------|
| Revenue | \$59.9M | \$59.9M | 6% |
| Net Income (loss) | (\$181.2M) | \$16.5M | 27% |
| EPS – Diluted | (\$3.92) | \$0.28 | 22% |
| EBITDA | (\$169.3M) | \$27.4M | (2%) |

| Balance Sheet | End 6/30/17 | Change | End 12/31/16 |
|--|-------------|------------|--------------|
| Cash, Cash Equivalents and Restricted Cash | \$84.9M | (\$113.6M) | \$198.5M |
| Notes Payable | \$291.5M | \$1.0M | \$290.5M |
| Net Debt | \$206.6M | \$114.6M | \$92.0M |

Financial Expectations for 2017

| Guidance (\$'s M) except EPS | Full Year 2017 Guidance |
|------------------------------------|-------------------------|
| Revenue | \$220 – \$230 |
| Adj. Net Income | \$56 – \$66 |
| Adj. EBITDA | \$109 – \$119 |
| Adj. EPS | \$1.00 – \$1.10 |
| Free Cash Flow | \$86 – \$96 |

Vtesse will be accretive to earnings beginning in 2019

Investment Highlights

- Global biopharmaceutical company focused on specialty areas with high unmet medical needs
- Late stage pipeline with 3 phase 3 programs with data readouts over next 12-24 months
 - VTS-270 for Niemann-Pick Disease Type C1 (NPC) from recent acquisition of Vtesse, Inc.
 - CPP-1X/sul Combo in Familial Adenomatous Polyposis (FAP)
 - Life-cycle management programs for lubiprostone
- Two marketed and outlicensed products in gastroenterology and ophthalmology providing >\$200 million in annual revenue and significant operating cash flow to fund pipeline and operations and limit downside risk
 - AMITIZA for constipation
 - RESCULA
- Focused business development strategy focused on capital efficient, highly specialized diseases to bolster growth and diversify
- Deep management team with proven ability to transform the company, create value, and commercialize products