

# **Chiasma, Inc.**

Fact Sheet

**CHMA**

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# CHIASMA

## QUICK REFERENCE

**Chiasma, Inc.**

**NASDAQ: CHMA**

Outstanding Shares: **24,389,666**

Website: [www.CHIASMA.com](http://www.CHIASMA.com)

## BUSINESS SUMMARY

Chiasma is focused on improving the lives of patients who face challenges associated with their existing treatments for rare and serious chronic diseases. Employing its Transient Permeability Enhancer (TPE®) technology platform, Chiasma seeks to develop oral medications that are currently available only as injections. In October 2018, the Company completed enrollment in CHIASMA OPTIMAL, its third Phase 3 clinical trial for its octreotide capsules product candidate, conditionally trade-named Mycapssa™, for the maintenance therapy of adult patients with acromegaly in whom prior treatment with somatostatin analogs has been shown to be effective and tolerated. Prior to trial initiation, the Company reached agreement with the FDA on the design of the trial through a special protocol assessment. Chiasma is headquartered in Waltham, MA with a wholly-owned subsidiary in Israel. Mycapssa, TPE and CHIASMA are registered trademarks of Chiasma.

## TECHNOLOGY

Chiasma's proprietary Transient Permeability Enhancer (TPE®) technology platform is designed to enable the development of oral forms of medications that are currently only available as injections. TPE aims to protect drug molecules from digestive enzymes and to trigger the temporary expansion of tight junctions between cells of the intestinal epithelium, a naturally occurring process. As a result, drug molecules may pass into the blood stream while larger structures such as toxins, bacteria and viruses are excluded.

TPE's ability to enhance oral bioavailability is the result of a combination of excipients that create a lipophilic suspension of solid hydrophilic particles in a hydrophobic medium. In all chronic toxicology and clinical trials, there have been no TPE-related safety signals or formulation-related adverse events. The adverse events that have been detected were associated with side effects of the study drug itself and the underlying disease.

## PRODUCTS

Chiasma's octreotide capsules (conditionally trade named Mycapssa®), are being developed for the maintenance treatment of acromegaly, a rare, serious chronic disease typically caused by a benign tumor of the pituitary gland that releases excess growth hormone (GH), leading to excess growth of certain parts of the body.

We believe octreotide capsules exhibit the effects of somatostatin, a naturally occurring hormone that reduces the production of GH by binding to receptors on specialized cells in the pituitary gland. There are currently no approved oral formulations of octreotide. Octreotide capsules were developed using Chiasma's proprietary Transient Permeability Enhancer (TPE®) technology platform designed to facilitate gastrointestinal absorption of unmodified drug into the bloodstream safely. The company completed an international Phase 3 trial of octreotide capsules, the results of which have been published in the Journal of Clinical Endocrinology and Metabolism.

Chiasma is conducting a Phase 3 clinical trial, referred to as "CHIASMA OPTIMAL" (Octreotide capsules vs. Placebo Treatment In MultinationAL centers) under a Special Protocol Assessment agreement reached with the U.S. Food and Drug Administration (FDA) to support a potential resubmission of a New Drug Application with the FDA. CHIASMA OPTIMAL is a global, randomized, double-blind, placebo-controlled, nine-month trial. The trial is designed to evaluate the proportion of patients who maintain their biochemical response to octreotide capsules compared to placebo. The company completed enrollment with 56 adult acromegaly patients in CHIASMA OPTIMAL in October 2018 and anticipates the release of topline data from this Phase 3 clinical trial in Q3 2019.

## CONTACT INFORMATION

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## Recent Press Releases *(Headlines and Excerpts)*

### Chiasma to Participate in Three Investor Conferences in March

March 04, 2019 -- Chiasma, Inc. announced that Mark Fitzpatrick, Chief Executive Officer and William Ludlam, MD, PhD, Senior Vice President of Clinical Development and Medical Affairs, will be presenting at the Cowen 39<sup>th</sup> Annual Health Care Conference and the Barclays Global Healthcare Conference. In addition, Mark Fitzpatrick will be participating in a fireside chat at the ROTH Capital Partners 31<sup>st</sup> Annual ROTH Conference.

- **Cowen 39<sup>th</sup> Annual Health Care Conference**  
Date: Monday, March 11, 2019  
Time: 2:10-2:40pm E.T.  
Location: The Boston Marriott Copley Place, Boston, MA
- **Barclays Global Healthcare Conference**  
Date: Thursday, March 14, 2019  
Time: 10:45-11:10am E.T.  
Location: Loews Miami Beach Hotel, Miami, FL
- **ROTH Capital Partners Annual ROTH Conference – Fireside Chat**  
Date: Monday, March 18, 2019  
Time: 8:00-8:30am P.T.  
Location: The Ritz-Carlton, Laguna Niguel, CA

### Chiasma Announces Support for Rare Disease Day 2019

Feb. 28, 2019 -- Chiasma, Inc. announced its support for the patient and research communities in recognition of Rare Disease Day 2019.

"The theme of Rare Disease Day 2019, 'Bridging health and social care,' strikes at the heart of what we are working towards here at Chiasma to improve the lives of people afflicted with acromegaly," said Mark Fitzpatrick, President and Chief Executive Officer of Chiasma. "Monthly somatostatin analog injections, the current standard of care for the maintenance treatment of acromegaly, are painful, can cause injection site reactions and also carry significant treatment burdens to some patients who report ongoing symptoms that interfere with daily life and leisure activities."

"Our octreotide capsules product candidate, which we have conditionally trade-named Mycapssa®, has the potential to become the first oral somatostatin analog in an injectable-only market. If approved, we believe it has the potential to reduce the treatment burdens associated with current acromegaly care in some patients. We are grateful to the policy makers, researchers, companies and healthcare professionals who continue to call attention to unmet medical needs in these rare and often debilitating diseases, and we look forward to advancing Mycapssa® through our two Phase 3 clinical trials and toward planned commercialization as we pursue our mission of enhancing the lives of people suffering from acromegaly."

Rare Disease Day takes place on the last day of February each year. The main objective is to raise awareness among the general public and decision-makers about rare diseases and their impact on patients' lives. For more information about Rare Disease Day, please visit [www.rarediseaseday.org](http://www.rarediseaseday.org).

### Chiasma Previews Important Upcoming Milestones

- **CHIASMA OPTIMAL Phase 3 topline data expected in Q3 2019**
- **Company anticipates submitting U.S. NDA by year-end 2019, assuming positive CHIASMA OPTIMAL data, and if accepted for filing, further expects a six-month FDA PDUFA review classification**
- **Key U.S. commercial readiness activities planned in 2019**

Jan. 03, 2019 -- Chiasma, Inc. today previewed anticipated upcoming corporate milestones and commented on the significant progress made by the company in 2018.

"During 2018, we completed the required enrollment in both of our Phase 3 clinical trials of our investigational octreotide capsules product candidate, which we have conditionally trade-named Mycapssa®, and with those trials progressing as planned, we believe we have set the stage for a catalyst-rich 2019 including the announcement of topline data evaluating Mycapssa's efficacy as potentially the first oral somatostatin analog for the maintenance therapy of adult acromegaly patients," said Mark Fitzpatrick, President and Chief Executive Officer of Chiasma. "As we enter the new year, our plans are firmly in place, assuming positive Phase 3 CHIASMA OPTIMAL data, to submit an NDA by the end of 2019 with an eye toward possible FDA approval of Mycapssa in mid-2020."

This Company Fact Sheet is distributed by Andrew Barwicki, Investor Relations. Contact Info: 516-662-9461 / [andrew@barwicki.com](mailto:andrew@barwicki.com)

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Permit No. 431

# Chiasma, Inc.

NASDAQ Trading Symbol: CHMA

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