



# Rosuvastatin Oral Solution (a 505B2 NDA Product)

**Shashikanth Varala**  
**Mobile:(+44)7505457665**  
**Email:shashi@mahashiv.co.uk**  
**Mahashiv Limited**  
**Unit 1, Kataria Point, 1 Riches Road,**  
**Illford, England, IG1 1JH**

**Rob Camerer**  
**Mobile: (417) 770-4600**  
**Tel: (417) 885-7000**  
**Email: robcamerer@globalpharmapartners.com**

## RLD PRODUCT NAME

Crestor ® Tablet, 5 mg, 10 mg,  
20 mg, and 40 mg

## API NAME

Rosuvastatin Calcium

## DOSAGE FORM

Oral Solution, 20mg/5ml

## INDICATION

Cholesterol

## PATENT STATUS

Mahashiv owns Patent Pending for the product and technology

## PARAGRAPH IV CERTIFICATION

NA

## ANDA FILER

NA

## POTENTIAL COMPETITORS

No generic competition

## EARLIEST GENERIC LAUNCH

NA

## Timelines for Developing Brand XXXXXX ®

- Definitive Agreement – Q3 2023
- Completion of 3×3 exhibit (pivotal) batches of drug product:Q4 2023
- 6 Month stability completion: Q3 2024
- BE study completion: Q2 2024
- Estimated FDA filing date:Q3-4 2024
- FDA approval: Q4 2025

## Terms for US Partner:

- Total Milestone payments: \$750,000
  - \$175,000 on signing
  - \$175,000 on Bioequivalence study Acceptance
  - \$200,000 on 505(b)(2) filing to FDA
  - \$200,000 on FDA Approval
- Filing Fee: Partner pays upfront (recoup 50% of fee from profits)
- Profit sharing: DP 50%/ 50% Partner
- Length of Term: 10 years

## Estimated Remaining Development Costs (50% DP/50% Partner):

- Formulation Development Cost: \$500,000
- Submission batches: \$ 200,000 (India) (5 batches- 3 validation and two feasibility batches; includes API cost of \$4,000)
- Bioequivalence studies: \$250,000
- Stability & non-clinical studies:\*\$100,000

+ Please note that the submission batches costs from India, should we move to EU/US CDMO, then costs will increase.

## Estimated Commercial Finished Dose Cost

COG: \$10.00 per unit-dose bottle pack (150ml) includes packaging, shipping, insurance etc. Please note that these COGS are based on manufacturing in India, should we move manufacturing to EU/US CDMO, then costs will increase.