



BDA-12

Breakthrough technology in pain control

Company Overview

Since its formation in 2004, BDA-12 LLC has focused exclusively on researching and developing new anesthetic/analgesic solutions—work that the company's founder, Glenn Abrahamsohn, began more than twenty years ago. The company has established proprietary formulations and completed pre-clinical toxicology work and validation studies, and it is actively pursuing commercialization strategies to bring its innovative products to market.

What is BDA-12?

- Breakthrough technology in pain control, providing reversal of anesthesia but continued pain relief, allowing patients to regain their sensation while retaining analgesic effect
- The company refers to this result as Local Anesthesia Analgesia Without Numbness (LAAWON)

Product Overview

Market

- BDA-12 has potential applications in three markets: dental, medical, and animal health, representing an estimated \$15 billion in total market opportunity

Product

- The product works as a reversal agent, restoring sensation after various dental, medical, and veterinary procedures while continuing pain relief
- The product has two formulations: BDA-12 and BDA-12Plus

Competitive Advantage

- The main competitor OraVerse® reverses local anesthetic but allows patients to begin feeling pain once numbness has subsided
- BDA-12 uniquely creates LAAWON, thus providing post-operative pain relief

IP

- 3 patent applications have been filed protecting the various formulations and uses of BDA-12 and BDA-12Plus (one application allowed in May 2014 and two pending)

Team

- Collectively, the executive team brings over 100 years of experience in dentistry, entrepreneurship, and executive leadership in the biopharmaceutical industry

Problem

Patients, Physicians, and Payers Experience Problems with Current Post-Surgical Pain Relief and Numbness

Patients

Patients often experience numbness and lack of sensation after receiving anesthetics for dental and surgical procedures, inhibiting them from quickly returning to their daily lives

Physicians

A physician's current options to mediate pain control often include side effects like nausea, bleeding, ulceration and addiction

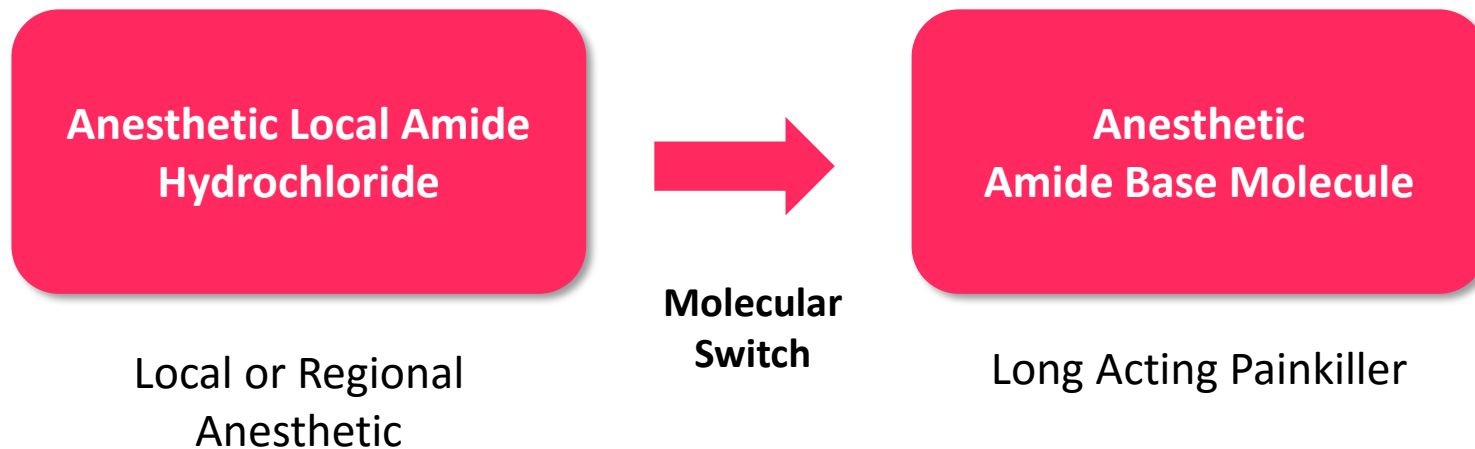
Payers

Whether patients are undergoing dental or medical procedures or require inpatient or outpatient care, there is a need for pain control techniques that allow patients to resume day-to-day activities with minimal delay

Solution

- BDA-12 is a breakthrough technology in pain control, providing reversal of anesthesia with pain relief
 - BDA-12 allows patients to regain sensation while retaining analgesic effect
 - The company describes the effect of this technology as Local Anesthesia Analgesia Without Numbness (LAAWON)
- The company's studies suggest that the mechanism of action of the product involves a molecular switch
- Currently there are two proprietary formulations:
 - BDA-12
 - BDA-12Plus

Mechanism of Action for LAAWON

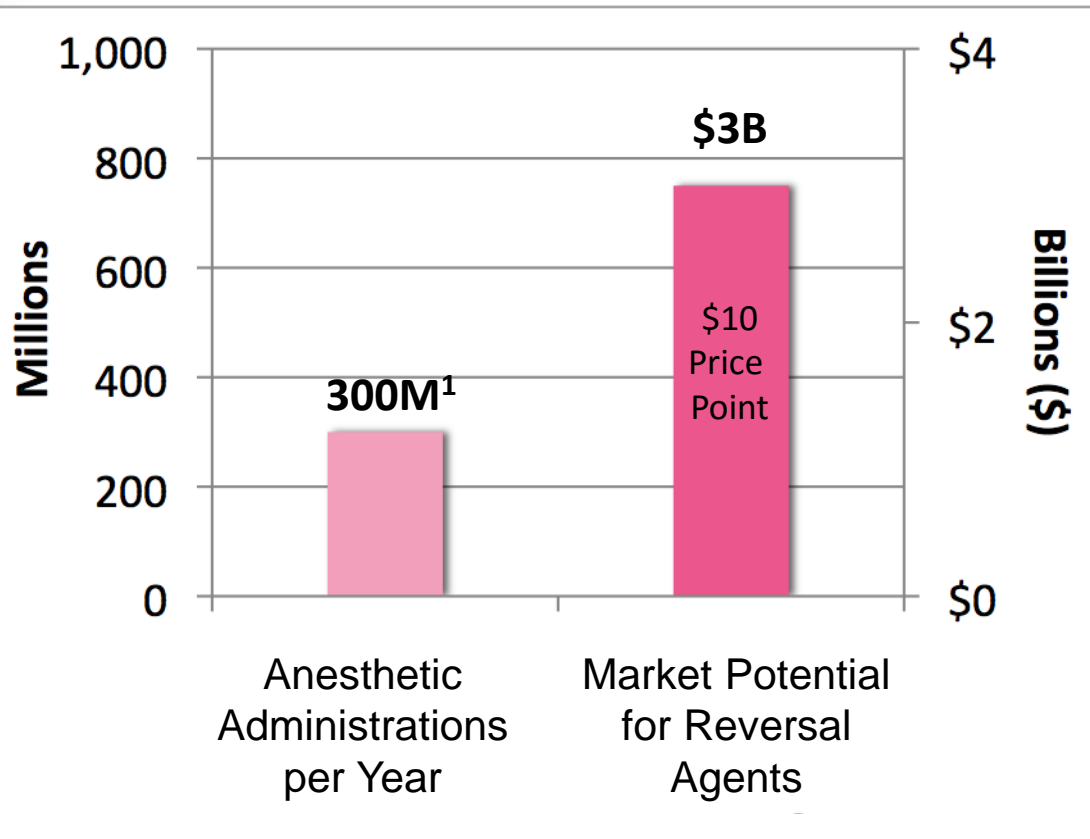


By “flipping” the amide hydrochloride molecule to its partially soluble base molecule, it creates a depot of slow-release, opiate-type pain killer in the tissue while allowing full sensation to return to the patient.

Market: Dental

The Dental Market is an Estimated \$3 Billion Dollar Opportunity

Dental Market, Reversal Agent

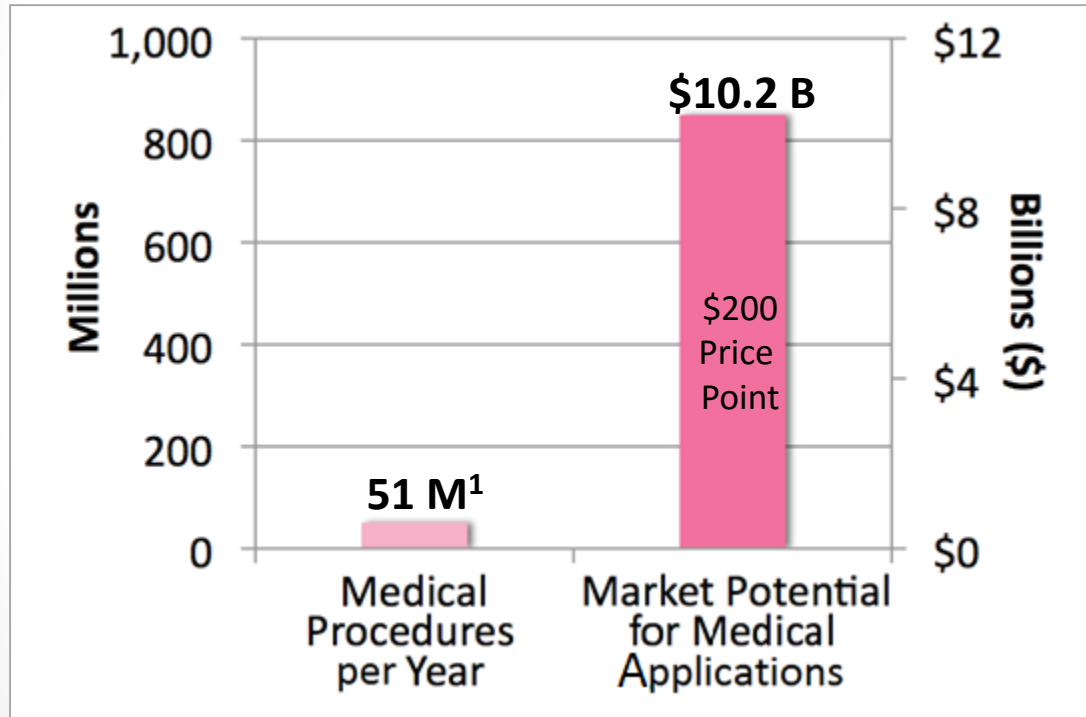


- There are about 300 million local anesthetic administrations per year in the US
- At a \$10 price point, the opportunity to participate in this market is estimated to be >\$3 billion

Market: Medical

The Opportunity for BDA-12 in the Medical Market is Estimated to Exceed \$10 Billion

Medical Market, Reversal Agent

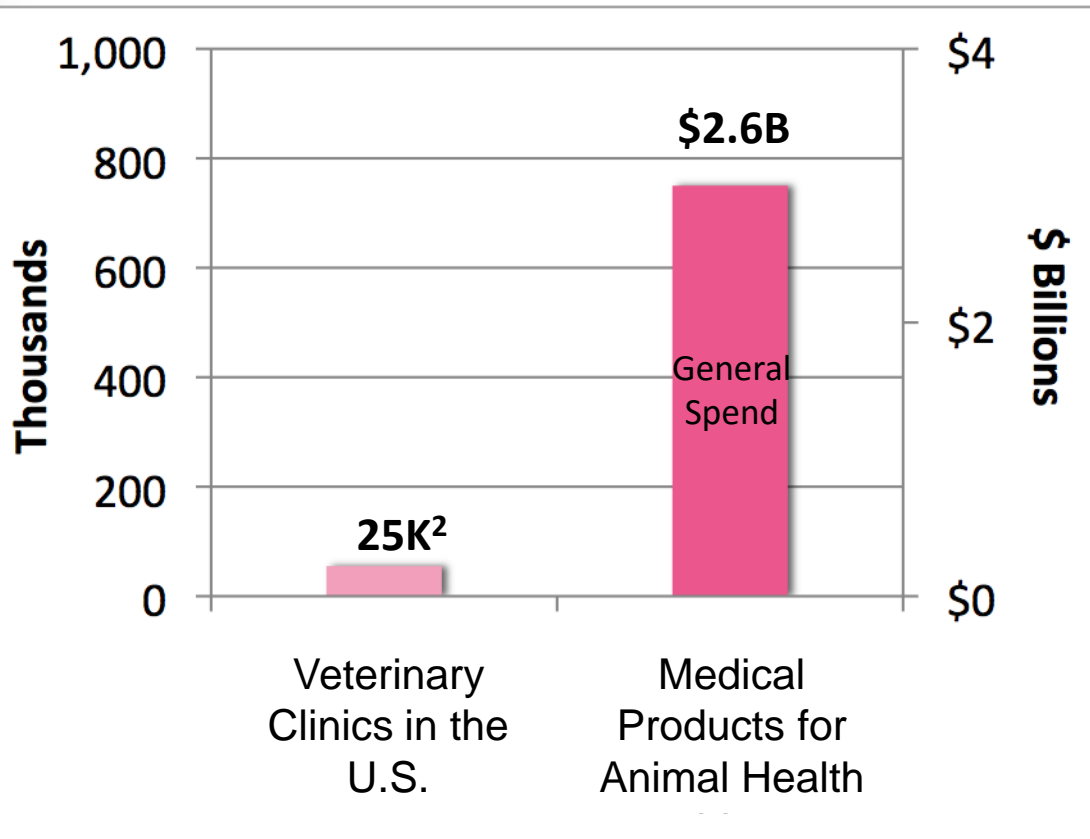


- More than 51 million surgical procedures are performed in the US each year
- At a \$200 price point for a sterile medical reversal kit, this represents an estimated \$10 billion opportunity to participate in this market
- BDA-12 is expected to be suited for pain reversal in epidurals, hand surgeries, hip surgeries, and other regional blocks

Market: Animal Health

The Animal Health Market Represents an Additional Estimated \$2.6 Billion

Animal Health Market, Reversal Agent



- There are 55,000 veterinarians practicing in 25,000 animal clinics in the US¹
- US spend on medical products for animal health is roughly \$2.6 billion per year²
- BDA-12 intends to participate in this market
- BDA-12 reverses the numbness and creates a pain killer, thereby reducing the likelihood that the animal will bite, chew, or damage its tissue

Market Research Studies

A Large Majority of Dentists Report Intent to Purchase BDA-12

Would you use a reversible anesthetic in private practice?¹

Yes	66.6%
No	33.4%

Percentage of the procedures in which dentists perceive a need to shorten or reverse anesthetic action.¹

Long-acting anesthetic	50.8%
Short-acting anesthetic	44.2%

Based on your knowledge of BDA-12, please indicate your likely purchase intent .²

Definitely purchase	35%
Most likely purchase	42%
Maybe purchase	17%
Most likely not purchase	5%
Definitely not purchase	1%

- The company commissioned a market research survey of dentists and their perceptions of reversal agents, in general
- The majority of dentists (66.6%) reported willingness to use a reversible anesthetic
- A second study, which provided specific information about the reversal properties of BDA-12, showed a large majority of dentists (77% in total) saying that they would “Definitely purchase” or “Most likely purchase” BDA-12

Sources:
1. Market research study by Key Biscayne Research Associates (N=153).
2. Market research study commissioned by Septodont, Inc. (N=99).

Competitive Landscape

BDA-12 Has Distinct Advantages Over Competition

	OraVerse®	BDA-12
Reduces unwanted, lingering numbness	✓	✓
Targets functional deficit after intraoral injection	✓	✓
Uses beyond lip and tongue		✓
Medical and Veterinary applications		✓
Non-vasoconstrictor agent		✓
Reverses numbness and creates a pain killer		✓
Avoids need for oral administration of pain relievers		✓
Avoids nausea and other side effects associated with pain relievers		✓

The company believes that the main competitor on the market is OraVerse® (Phentolamine Mesylate; Septodont). Importantly, the OraVerse® use of a vasoconstriction agent simply shortens analgesic duration, allowing pain sensation to return to the patient. In contrast, the breakthrough technology in BDA-12 and BDA-12Plus truly reverses numbness, thereby restoring sensation while continuing analgesic activity. OraVerse® was acquired by Septodont in 2011 for an undisclosed sum, illustrating potential exit opportunity for investors and further validating the attractiveness of investing in the pain control space.

Intellectual Property

US Patent BDA-12

- Method using BDA-12 alone for providing LAAWON
- Status: Allowed May 2014

PCT* BDA-12 Plus

- Method using BDA-12 with additional actives for providing LAAWON
- Status: Pending

Provisional Topical

- Compositions and methods using BDA-12 alone, and BDA-12 with additional actives for providing LAAWON
- Status: Pending

*PCT = Patent Cooperation Treaty

Business Model and Development Plan

The Company Has Devised an Organized Approach to Reach Market

Business Model

- BDA-12 is expected to be sold in 1.8ml dental cartridges to dentists, and in sterile packs to physicians and veterinarians
- It is expected that doctors/surgeons will be reimbursed by one of the following methods:
 - Cash payments from patients
 - Building the product cost into the cost of the procedure
 - Payment from third party insurers

Development Plan

- Dental application is the most advanced and will likely be the first application to achieve sales. On successful market launch, development of medical application is expected to follow, along with subsequent veterinary application

Gross Earnings Estimate

Year	Dollars
FY1	(\$5,400,000)
FY2	\$38,000,000
FY3	\$95,000,000

- Positive cash flow expected in 3Q FY2
- Break even expected to occur within first two years

Raise and Use of Proceeds

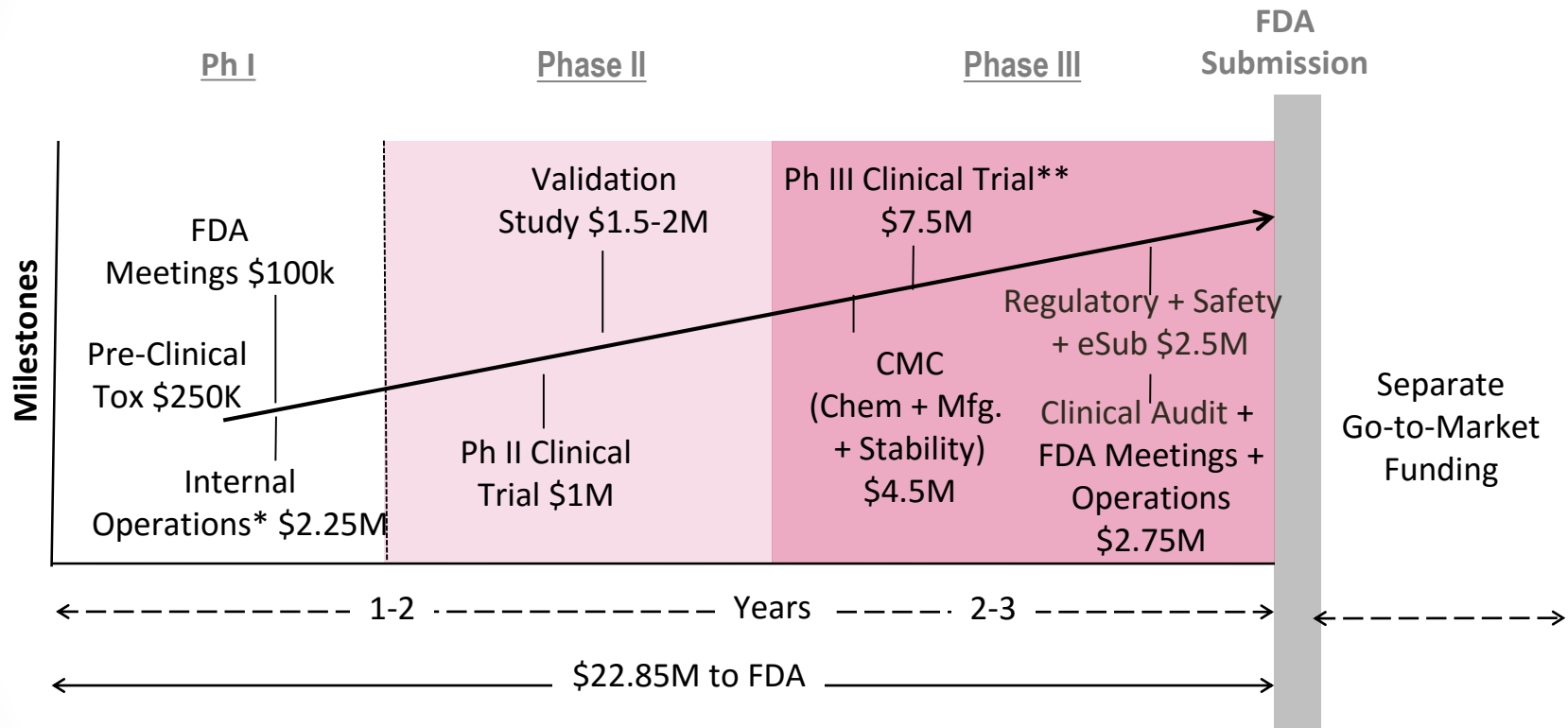
1st Round Financing

- The company is seeking \$22.85 million to complete development of BDA-12 in dental application
- Proceeds expected to finance CMC, stability testing, clinical studies, operational costs, unforeseen FDA requirements, and NDA submission to the FDA for dental application of BDA-12

Future Financing

- Additional funding will likely be sought for:
 - Dental market launch
 - Medical application (development and market launch)
 - Veterinary application (development and market launch)

Projected Costs to FDA Approval for BDA-12 for Dental Application



The company seeks to raise \$22.85M to fund clinical trials of BDA-12 for dental applications to include chemistry, manufacturing and controls (CMC), stability testing, regulatory submissions, FDA meetings, safety reporting, project management, operations, and consultants. Additional funds will be required for Go-to-Market execution and for medical and veterinary applications.

*Includes costs for space, regulatory, legal, consultants, and executive management salaries

**Includes costs for clinical sites, IRB, patient Recruitment, CRO, and insurance

Executive Team

Glenn Abrahamsohn, LDS, RCS (Eng), *Chief Executive Officer & Founder*

- 30 years experience in dentistry
- 20 years working with anesthetic solutions
- Extensive publications in peer-reviewed journals

Mark Kirn-Slaboszewicz, MA, *Chief Advisor*

- 32 years executive leadership in biopharmaceutical industry
- Former President, Schering-Plough Healthcare Products
- Additional leadership roles at Sterling Drug and American Cyanamid

Benjamin Lewis, PhD, RPh , *Regulatory Affairs Executive and Scientist*

- 30 years experience at FDA: Director, Regulatory Operations
- Developed and successfully submitted multiple INDs and 8 NDAs
- Head Regulatory Affairs, N. America at Mitsubishi; VP Regulatory Affairs at Prestwick

Dean Rodwell, MS, *Research & Development Executive*

- 40 years experience in toxicology, GLP, and drug development
- Executive experience in roles such as VP (IIT Research Institute), President (Huntingdon Life Sciences), and COO (BioDuro)

IP Counsel and Advisors

Ted Whitlock, JD *Intellectual Property Counsel*

- 20 years experience in IP law
- Expertise in freedom-to-operate, licensing, and IP litigation for biopharmaceutical and biomedical companies
- Formerly Partner at Davidson, Davidson & Kappel LLC

Richard Dulik, JD, *Intellectual Property Counsel*

- 18 years experience in IP law
- Expertise in patent prosecution, counseling biotechnology and internet start-ups, technology exports, and licensing
- Adjunct Professor of Law at Georgetown University

Doug Nordlinger, JD, *Corporate Attorney*

- 30 years of experience in joint ventures, M&A, and project financing
- Partner at Skadden, Arps, Slate, Meagher & Flom
- Additional experience with regulatory agencies

Faith Charles, JD, *Corporate Transactions and Securities*

- 25 years of corporate transactional experience
- Partner at Thompson Hine
- Leads Thompson Hine's Life Sciences group

Matthew Vaughan, JD, *Corporate Transactions and Securities*

- Associate at Thompson Hine
- Focus on early stage and emerging companies at Thompson Hine
- Experience in private equity and venture capital transactions

Yuxin Zhang, PhD, *Statistician*

- 15 years in statistics for the pharmaceutical industry
- 12 years Former Head of Biometrics & Data Management at Shire Ltd
- Outstanding track record of NDA approvals

Contact



Glenn Abrahamsohn, L.D.S., R.C.S., (Eng.)
Founder & CEO

*BDA-12 LLC
260 Crandon Boulevard
Key Biscayne, FL 33149
(305) 361-0778*

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