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Less painful, faster-acting, more reliable dental injections

Making dental injections less painful, faster-acting, and more reliable



Problem / Market Need

- Dental injections are notoriously painful, slow-acting, and unreliable
- 90% of dentists surveyed reported that they want a better anesthetic

Lead product (Libracaine Dental)

- New, highly-differentiated, best-in-class dental anesthetic Lidocaine 2% / Epinephrine 1:100,000 buffered to pH 7.0
- TPP (vs SOC): Faster-acting, less painful, more reliable; with identical safety, depth/duration of anesthesia, shelf-life
- No change in clinical practice, no new equipment or protocols
- < 1% of procedure cost, no cost to patients, no payor involvement

Enabling Technology Platform / Intellectual Property

- Patented cartridge technology improves drug performance, including local anesthetics, without loss of shelf-life
- 2 granted patents expiration Q1 2038 (~12 yrs. post-launch)
- 1 pending patent expiration Q1 2044 (~18 yrs. post-launch)

Market Validation

- 96% of dentists surveyed reported likely to purchase Libracaine
- > 150 clinicians (end-users) invested \$2.1 MM in early rounds

Regulatory

- 505(b)(2) NDA regulatory path agreed on with FDA
- Minimal time, expense, risk; NDA approval target Q4 2026

Market Size / Competitive Landscape

- Market dominated by two old generics with nearly identical profiles
- NA/EU/JP/ROK SAM: 744 MM units/yr. (of 1.9 B units/yr. WW TAM)
- Peak share of SAM (SOM/SAM) est. @ 35% (260 MM units/yr.)

Business Model / Forecast

- Wholesale sales through existing distribution channels
- Target AWSP/ARSP: \$3.00/\$4.00
- Base case revenue/income forecast at peak: \$1.6 B / \$1.1 B

Current Raise

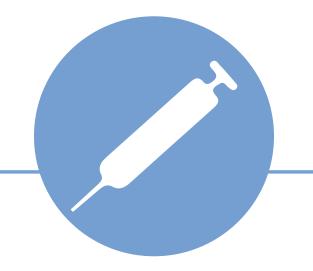
\$20 MM priced equity – months 1-24

Development & Commercialization Use of Funds / Timing

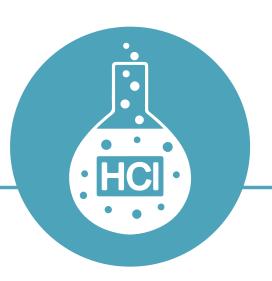
- \$6 MM equity, months 1-12: Registration batch, IND submission
- \$4 MM equity, m. 1-12: Initiate comm. mfr. line
- \$10 MM equity, m. 13-24: Small clinical, NDA submit; Install comm. line
- \$7 MM equity, months 25-32: US launch; Revenue



https://balancedpharma.com/demo



Dental injections are notoriously painful, slow-acting, and unreliable.



Hydrochloric acid, a preservative in the current drugs, causes all these issues.



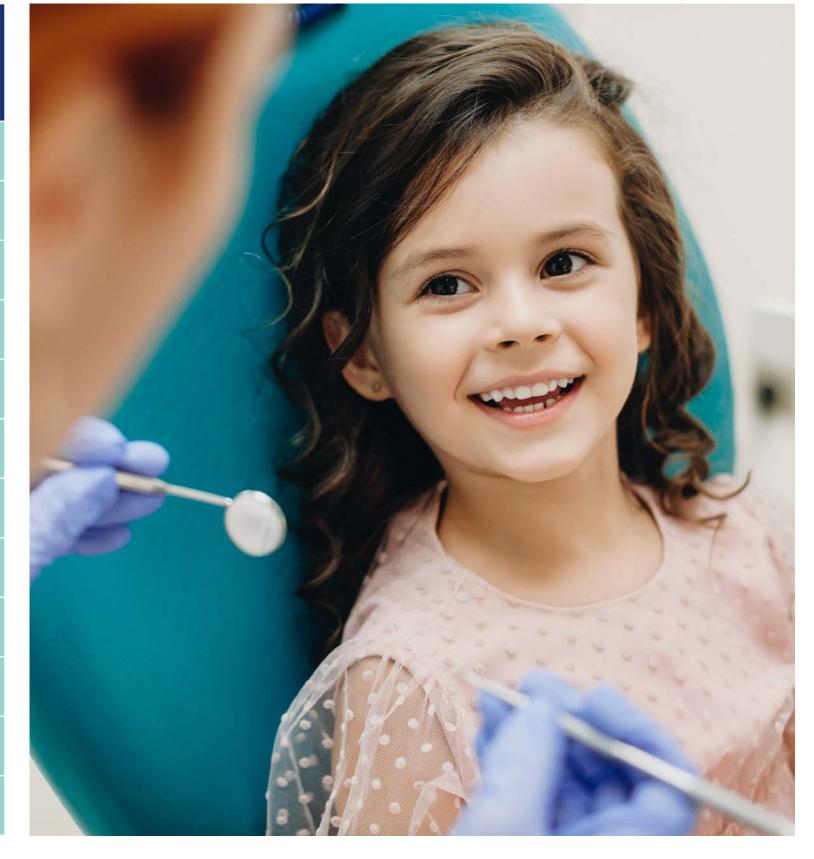
No way currently exists to provide an acid-free anesthetic in a standard dental cartridge.

Libracaine Dental: A pH-balanced reformulation of the most common dental anesthetic



Libracaine Dental¹ [lidocaine 2% / epinephrine 1:100,000, buffered with 0.7 sodium bicarbonate] TARGET PRODUCT PROFILE, compared with SOC lidocaine HCl 2% /epinephrine 1:100,000

Injection comfort	25% less painful ²
Anesthesia onset time	75% less latency ²
Reliability in inflamed teeth	33% more reliable ³
Shelf-life	Better - 33% longer
Salt balance (Osmolarity)	Better - isotonic
Acid balance (pH)	Better - neutral
Active ingredients (API)	Same as SOC
Anesthetic depth/duration	Same ²
Safety profile	Same ²
1.7 ml drug volume	Same
Technique / Protocol	Same
Use in standard dental syringe	Same



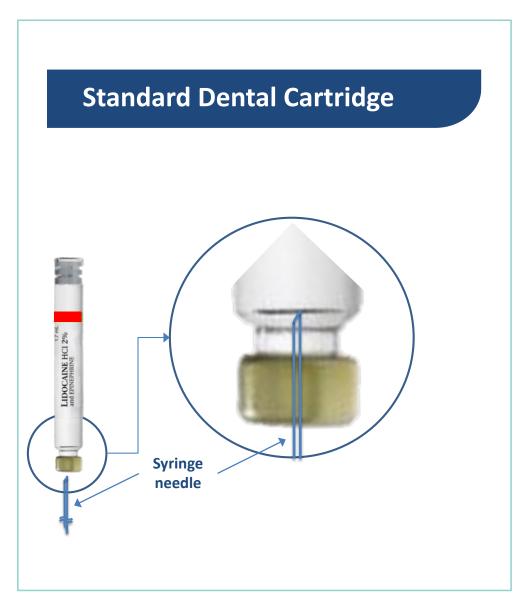
¹LIBRACAINE HAS NOT BEEN APPROVED BY FDA AND IS NOT AVAILABLE FOR SALE; ²2018 Meta-analysis: Guo et al from University of Southern California School Of Dentistry concluded: "Buffered lidocaine **significantly decreased onset time** and injection pain (VAS) compared with non-buffered lidocaine in inferior alveolar nerve block."; 2017 Clinical Study: Phero et al from University Of North Carolina School Of Dentistry concluded: "Buffered lidocaine reduces the pain on injection with a maxillary field block and results in similar lengths of pulpal anesthesia as non-buffered 2% lidocaine." 2017 Clinical Study: Warren et al from University Of North Carolina School Of Dentistry concluded: "After mandibular nerve block, buffered 1% lidocaine can produce similar duration of pulpal anesthesia as non-buffered 2% lidocaine and lower pain on injections."; ³2019 Meta-analysis: Kattan et al from University Of Pennsylvania School Of Dentistry concluded: "Buffered local anesthetics have **2.29 times greater likelihood of achieving successful anesthesia [in pulpally involved teeth]**.

Patented cartridge delivers a pH-neutral formulation, without loss of shelf-life

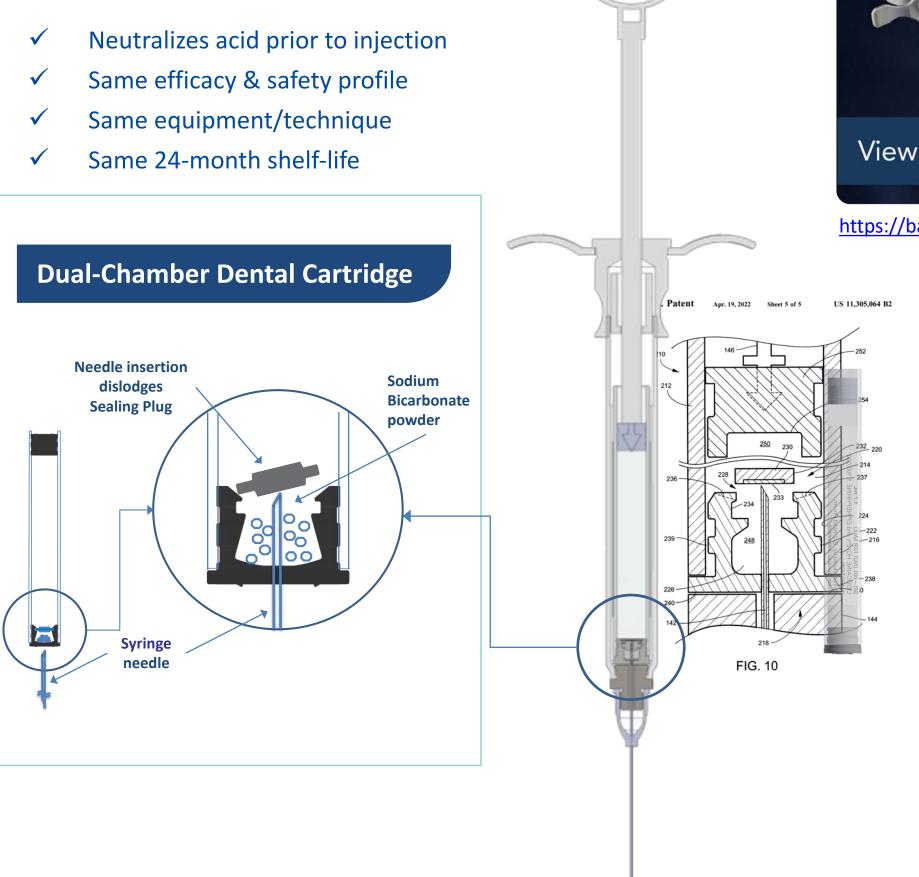


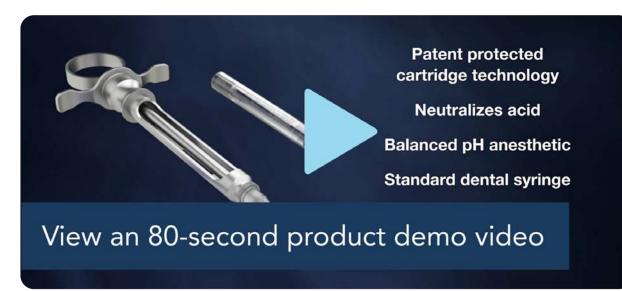
Incumbent SOC Dental Anesthetics

- Lidocaine 2% HCl with Epinephrine, or
- Articaine 4% HCl with Epinephrine
- Acidic injected solution (as low as pH 3.0)
- Acid causes sting and delayed onset

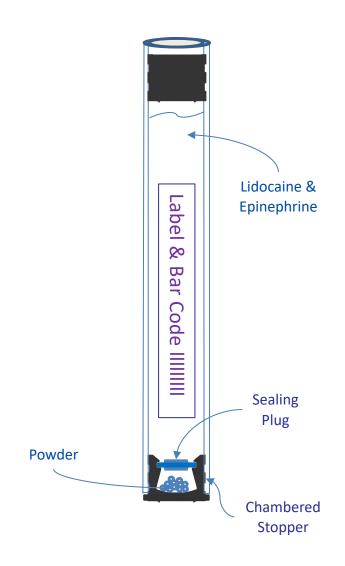


Libracaine Dental





https://balancedpharma.com/demo



Strong Positive Reaction from Dentists & Key Opinion Leaders





Are "likely to use Libracaine" 1,2



Think "using Libracaine will increase referrals" 1,2



Are "likely to feature Libracaine on their website and in their marketing materials" 1,2

A pH-balanced anesthetic in a standard dental cartridge will be a game changer.

- Jason Goodchild, DMD

Dr. Goodchild holds academic appointments at the University of Pennsylvania School of Dental Medicine, Rutgers School of Dental Medicine, and Creighton University School of Dentistry. He has authored more than 50 research papers on the subject of dental pain management.



balanced

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Libracaine Dental [BPI-001] – Regulatory Summary

LIDOCAINE HCl 2% with EPINEPHRINE 1:100,000; sodium bicarbonate 0.7% buffer

BPI-001 has a well-defined 505(b)(2) regulatory path with minimal expense, time & risk

FDA meeting minutes from 15 August, 2023, form the basis for our regulatory plan:

- BPI-001 is a drug submission (not a device or combination product) and a 505(b)(2) NDA is the appropriate approval path
- We plan the following non-clinical and clinical studies, at a total time & cost of < 18 months and < \$2 MM
 - Two-species neuro-toxicology to show local safety.
 - Small bio-equivalence to show systemic safety.
 - Small acute clinical study (n ~120) to show local anesthetic non-inferiority, faster onset time, and lower injection pain.
 - Small human factors study (n ~20) to show clinical functionality
- Strong existing evidence predicts that BPI-001, when compared with the reference drug (current SOC generic: Lidocaine 2% with Epinephrine 1:100,000), will demonstrate local safety, systemic bio-equivalence, non-inferiority of local anesthesia, faster onset time, lower injection pain, and clinical functionality

Balanced Pharma has retained ProPharma Group (formerly Weinberg Group)



ProPharma is among the leading experts in FDA Liaison

 ProPharma will oversee regulatory operations through approval including IND submission, clinical design, CMC activities and drafting of 505(b)(2)

Libracaine Dental [BPI-001] vs Other Dental Local Anesthetic Products



1	L 949	1973	2011	2026

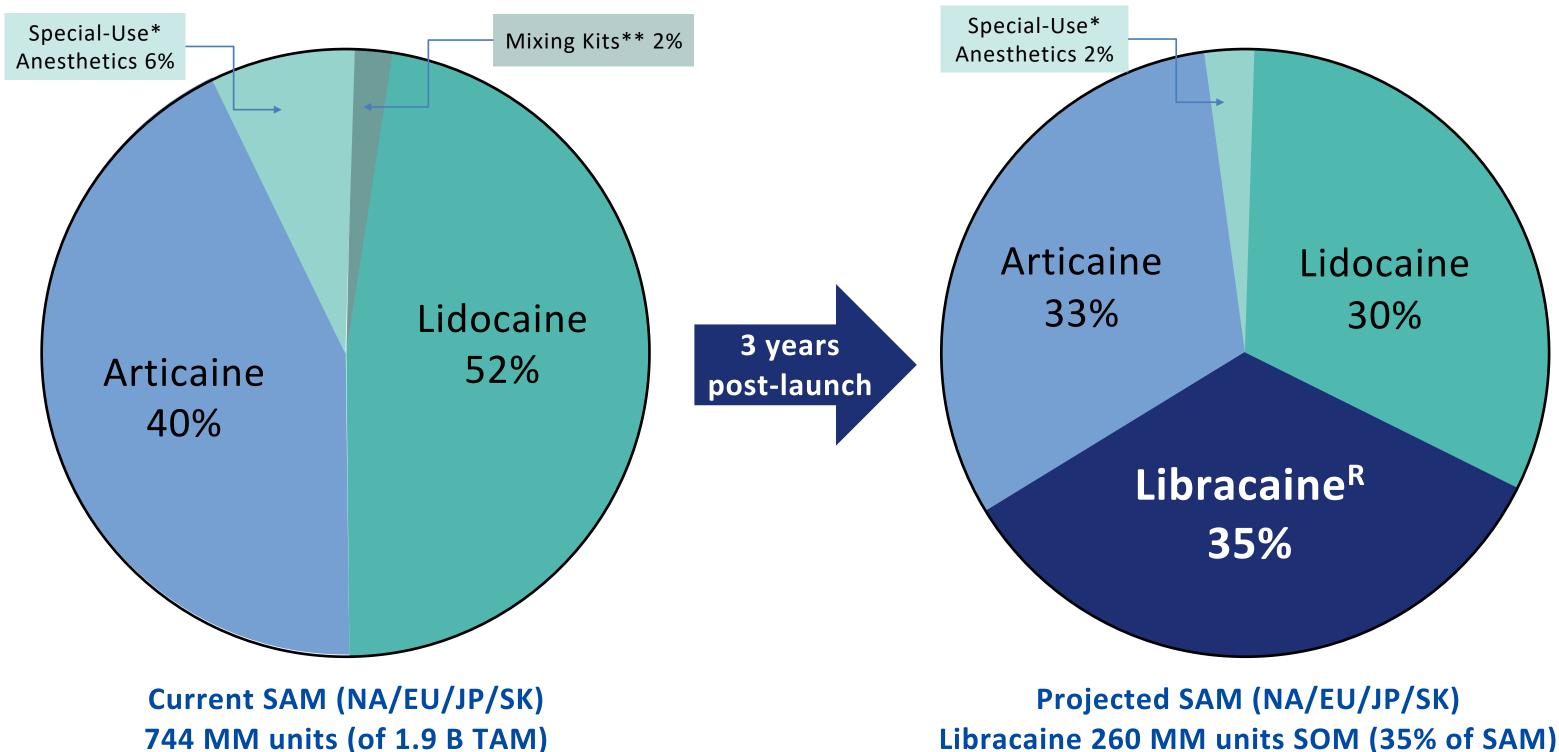
Product/Feature	Lidocaine (SOC)	Articaine (SOC)	Buffering devices	Libracaine [®] Dental
Market share	~50%	~40%	< 1%	Pre-launch
Less painful	No	No	Yes	Yes
Faster-acting	No	No	Yes	Yes
More reliable	No	No	Yes	Yes
FDA drug approval	Yes	Yes	No	Yes*
No mixing or training required	Yes	Yes	No	Yes
Standard dental cartridge	Yes	Yes	No	Yes
24-month shelf life	No	Yes	No	Yes
Current or est. avg. retail sale price**	~\$0.97	~\$1.12	~\$10.00	~\$4.00 (est.)

^{*}Libracaine has not been approved by FDA. BPI is currently pursuing a 505(b)(2) NDA.

^{**}Anesthetic expense (for Libracaine or current market leaders) represents less than 1% of the cost of a typical dental procedure.

Target SAM: Affluent markets with existing distribution channels in NA/EU/JP/SK





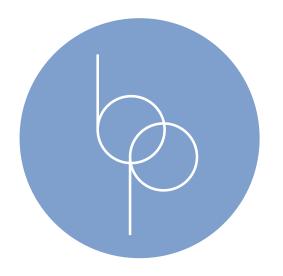
SDM Northcoast report, "Injectable Cartridges Market Size Analysis, United States, Canada, Mexico, 2019 Units", July 15, 2021; Key-stone Research, "European Local Anesthetics Market Survey," September 20, 2021; Balanced Pharma Internal Estimates. https://www.dentistrytoday.com/dental-pain-control-and-local-anesthesia-a-40-year-journey/ Libracaine 260 MM units SOM (35% of SAM)

Based on estimated 35% of SAM – Olson Research Group, "U.S. Dentist Quantitative Report, Aug 13th, 2021," n =181 Dentists; Key-Stone Research, "European Local Anesthetics Market Survey, Sep 20, 2021," n = 433 Dentists.

- *Mepivacaine, bupivacaine, and prilocaine are used in special circumstances, but are not typical stand-alone drugs for most procedures.
- **Mixing kits are devices intended to aid manual "physician-compounding" of anesthetics with buffering agents and are not FDAapproved drugs.

BPI will sell wholesale through existing distributors & expects ~67% operating margin





BPI will sell wholesale to well-established distributors

- AWSP est. \$3.00/unit
- COGS est. < \$1.00/unit
- EBIT to BPI est. >\$2.00/unit



Distributors will re-sell to end-user dentists

- ARSP est. \$4.00/unit
- Distributors will 5x profit on each unit compared to selling generic



Dentists do not bill patients or insurers for anesthetic

- Current drugs priced ~0.003 x procedure costs
- Libracaine est. price ~ 0.010 x procedure costs
- Est. ROI > 7x (marketing advantage + time saved)

Example Distributors

Atlanta Dental

Benco Dental

Darby Dental

Henry Schein Dental

Patterson Dental

Example Marketing Partners

Dentsply/Sirona

Inibsa

Pierrel

Septodont



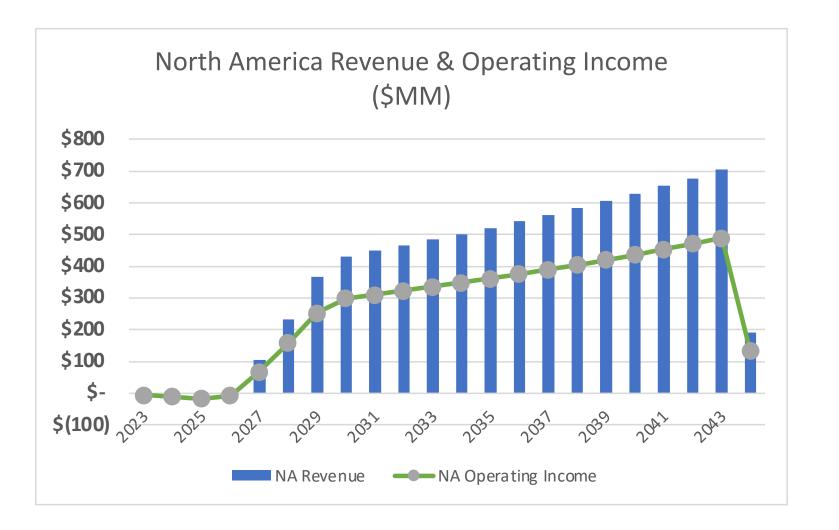
Base case forecast @ 35% peak market share

BALANCED PHARMA FORECAST - DRAFT FOR DISCUSSION ONLY

Key outputs in MM USD							
NA peak sales (\$MM)	704						
Europe peak sales (\$MM)	606						
Japan & S. Korea peak sales (\$MM)	283						
Cons. global peak sales (\$MM)	1,593						
Sum of distributions (\$MM)	10,229						
Risk-adj pre-tax NPV from today (\$MM)	3,398						

Key inputs							
Overall PoS (risk)	80%	AWSP/unit (all markets)	\$3.00				
Servicable Available Market (MM units)	744	Total mfr. costs/unit	\$0.87				
Peak NA share	35%	Marketing, sales costs (\$MM)	15.0				
Peak EU share	35%	Corporate G & A costs (\$MM)	2.2				
Peak JASK share	35%	Launch Timing - NA	2026.92				
Years to peak - NA	3	LOE - NA	2044.25				





\$9 MM equity raise enables registration batch, IND, tox, initiate commercial line mfr.



Months	0-3	4-6	7-9	10-12	13-15	16-18	19-21	22-24	25-27	28-30	31-33	34-36	37-39	40-42	43-45	46-48	49-51	52-54	55-57	58-60
R&D & Regulatory - \$8 MM	\$6 M	ſМ						\$2 MM	1											
Mfr. Registration Batch	Mfr. re	gistratior	n batch																	
IND & Pivotal (Phase III)			IND su & app	bmission roval		Pivotal	study													
Tox & Bio-equivalence			Tox &	Bio-equiv	alence stu	dies														
Stability				Stabilit	y & analy	sis														
NDA						NDA sul	omission	NDA ap	proval											
Commercialization - \$19 MM		\$3 M	ſМ		\$9 MN	M			\$7 MN	// *										
Manufacturing		Coı	mmercial N	Aachinery	Build & 1	Install (by	others) –	- 24 month	s	Pre-laur inventor) U.	S. launch	& revenue	e						
Brand, Marketing, Sales								Pre-mark Price/Vo			Brand, M	larketing,	Sales							
Finance Summary: \$27 MM Equity Investment to Profitability	\$20]	MM eg	uity						\$7 MI	M* equi	ity			Profit	ability					

^{*}Note: Total cash needs include ~\$19 MM in commercial debt to be collateralized by inventory.

Libracaine Dental [BPI-001] vs other life science opportunities



Large, Known, Existing Market	 Estimated 744 MM units/year in US/EU/Japan/ROK for current SOC products Estimated peak \$3.7B wholesale SAM & \$1.3B wholesale SOM for BPI-001
Long Patent Life	 Two granted patents, one patent pending Patent term and market exclusivity expected until Q1-2044
Very Low Regulatory Risk	 Buffered reformulation of well-known drug & indication All product components are well-characterized
Very Low R&D Cost, Fast Exit Potential	 Abbreviated 505(b)(2) FDA pathway Total runway to NOI < \$54 MM, launch & revenue potential in 33 months
No Change in Clinical Practice	 Standard dental cartridge works with all existing syringes No training or new protocols required
Ripe Competitive Landscape	 Only two incumbents, articaine & lidocaine, both decades-old generics Libracaine Dental will be highly-differentiated, best-in-class
No Reimbursement Issues	 Dental anesthetics are an incidental cost to dentists Libracaine Dental will be economical & comprise < 1% of procedure cost
Accessible Distribution Channels	 Wholesale sales to multiple distributors Well established distribution network; BPI-001 enables higher margins vs SOC generics
Proven Market Need	 Over 150 clinicians (end-users) invested over \$2.1 MM in early rounds 90 % of 614 US/EU dentists surveyed want at least one of our improved features

Expertise in Pharma, Dental, Finance, Regulatory, Manufacturing, & Commercial



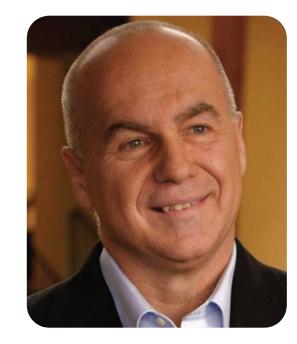


J. Scott Keadle, DDS
Chairman, Chief Executive Officer
Founder and CEO at Balanced Pharma,
30+ years as a dentist, practice owner
and business executive



John Selig
Director

Managing Partner at WaveEdge Capital,
25+ years in life science investment
banking and M&A practice



Mark Sebree
Director, *Chief Development Officer
Fmr. CEO, Becton Dickinson Rx; 35+ years in strategy, acquisitions, and operations in the pharma industry



*Chief Financial Officer

13 years experience in accounting advisory, auditing, and M&A; extensive experience in financial reporting



Jason Suggs
*Chief Communications Officer
CEO at Orange Reef, 20+ years
in brand strategy, communications,
and technology



Nita U. Patel, Ph.D.

*Senior Advisor—CMC

SVP, Global Reg. Issues and Head of CMC, at ProPharma Group; 30+ years of R&D and pharmaceutical industry experience



*Senior Advisor—Regulatory

EVP, Head of U.S. Regulatory Sciences, at ProPharma Group; 22+ years of pharmaceutical industry experience

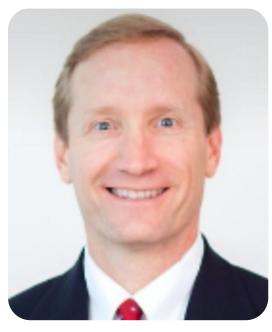


*Senior Advisor – Commercial

CEO, TruBlu Dental; Fmr. Dentsply-Sirona
Sr. Exec.; Fmr. Sr. Ext. Advisor, McKinsey &
Co. Pharma & Med Products Division



Sara Hanks, Esq.
*Outside Securities Counsel
CEO, CrowdCheck Law Firm



Byron Kirkland, Esq.
*Outside Corporate Counsel
Managing Partner,
Smith Anderson Law Firm

Scientific Advisory Board



Balanced Pharma's Scientific Advisory Board includes experts in Pharma, Dental Anesthesiology, Oral Surgery, and Dermatology.



Bishr Al-Dabagh,
MD, MBA, FAAD, FACMS
*Scientific Advisor

Board-certified dermatologist (American Board of Dermatology), fellowship-trained dermatologic surgeon (American College of Mohs Surgery), and a fellow of the American Academy of Dermatology (AAD). Dr. Al-Dabagh has published over 20 peerreviewed articles and book chapters.



Larina Chu, DDS, M-PA, CLS
*Scientific Advisor

Dentist anesthesiologist serving the greater Hesperia, California area. Dr. Chu is a professional member of the American Board of Dental Anesthesiologists, the American Dental Association, the California Dental Association and the Tri-County Dental Society.



Mark Donaldson, Pharm.D.
*Scientific Advisor

Associate Principal at Vizient Pharmacy
Advisory Solutions, 17+ years as a
recognized expert in dental
pharmacology, He holds academic
appointments at the University of
Montana and the Oregon Health &
Sciences University and serves on the
editorial board of the Journal
of the American Dental Association



Jay B. Reznick, D.M.D., M.D. *Scientific Advisor

Director of the Southern California
Center for Oral and Facial Surgery
in Tarzana, California; Diplomate
of the American Board of Oral and
Maxillofacial Surgery; the first
specialist in the U.S. to integrate CBCT
and CAD/CAM in his practice; has
been published extensively
in dental and medical literature



John B. Roberson, DMD
*Scientific Advisor

Oral & Maxillofacial Surgeon; CEO and Co-Founder of AAFDO (Accreditation Association For Dental Offices); CEO and Co-founder of the Institute of Medical Emergency Preparedness; author and lecturer; selected as a CE Leader for Dentistry Today for 10 consecutive years

Clinical Advisory Board



Balanced Pharma's Clinical Advisory Board includes over 75 practicing clinicians across every specialty that uses local anesthetic.



Mamta Patel, DDS

Dentist; Owner, Stamford

Dental Spa; University

of Connecticut; Licensed

in New York, Connecticut



Marcus Johnson,
DDS, MSD
Endodontist, Lecturer,
Teacher, Interfaith Hospital;
NYU College of Dentistry



Arthur DiMarco, DMD

Co-Author, Local Anesthesia
for Dental Professionals,
Professor, Eastern

Washington University



Kathy Bassett, BSDH, RDH, MEd, QOM

Co-Author, Local Anesthesia for Dental Professionals;

Prof., Univ. of Washington



Karin Davis,
DMD, MPAS, PA-C
Oral & Maxillofacial Surgeon;
Diplomate, National Dental
Board of Anesthesiology



Dean DeLuke, DDS

Professor Emeritus, Oral &

Maxillofacial Surgery, VCU;

Frequent Lecturer on Local

Anesthesia in Dentistry



Katie Post, DDS

Owner, Northwest Dental
Group; Board Member,
Ronald McDonald House;
University of Iowa



Ethan Chase,
DMD, CAGD

Dentist; Clinical Lecturer,
Boston University Goldman
School of Dental Medicine



Pedram Mastour, DDS

Dentist; Clinical Assistant

Professor, Division IV,

The Herman Ostrow School

of Dentistry, USC



Traci McCormick, MD

Radiation Oncologist; CEO
and Medical Director,

Precision MD Wellness;

Residency, Indiana University



Scott Harper, MD

Vice Chair, Department
of Anesthesiology, UAB;
Chief of Anesthesia,
St. Vincent's Hospital



Ivory Hancock, DMD

President, IVORY Dental

Centre, Washington, D.C.;

Temple University, NYU

College of Dentistry



Raymond Jone, DDS, FAGD, FICOI, DIDIA, Owner, Pacific Sky Dental; Columbia University School of Dentistry; USC



Elaine Vowell,
DDS, FAGD
Founder, Your Best Shot;
Creighton University
School of Dentistry



DDS, FICD

Commander, COL, U.S. Army

Dental Activity (DENTAC), HI;

Tripler Army Medical Center



Wenhong Peng,
DDS, MPH, MBA

Dentist; Owner, Peng Dental
Health; Harvard School
of Public Health; USC



Thank you for your consideration.

For further inquiry, please contact CEO Scott Keadle:

mobile 704-650-0249

Scott.Keadle@BalancedPharma.com

Appendix

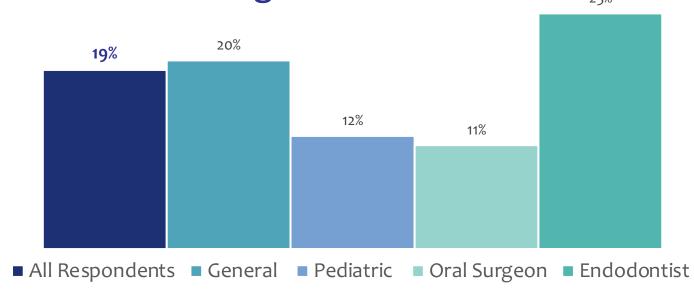
Slide(s)	<u>Title</u>
20	Market Need
21	Target Product Profile
22	Intellectual Property
23	Scientific Literature
24-26	Buffered Anesthetic Benefits
27	Provider Economics

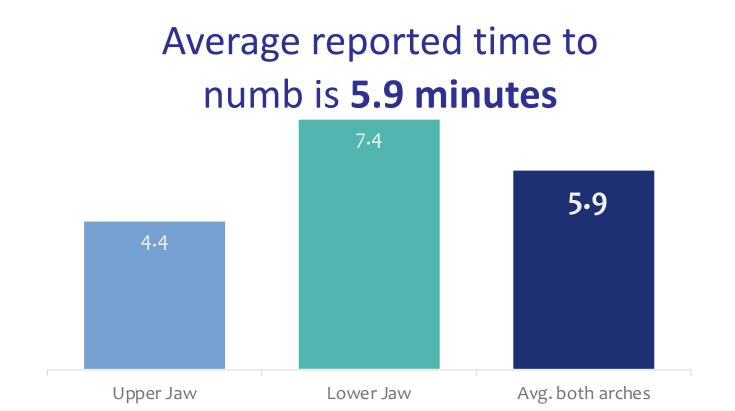
Dental injections: Plenty of room for improvement

58% of PATIENTS

say the **injection** is the **worst part** of the dental experience

Anesthetic difficulties are the cause of running late **19%** of the time





90% of dentists would change their current anesthetic to be one or more of the following:

Faster acting Less painful More reliable (56%) (56%) (47%)

^{*}All data presented on this page are based upon a market survey conducted by Olson Market Research in 2021 of 181 U.S. dentists and 150 U.S. patients.

TARGET PRODUCT PROFILE

Libracaine Dental vs lidocaine 2% / epinephrine 1:100k



Drug Product Feature	Xylocaine Dental 2% with Epinephrine 1:100,000	Target change from Reference Drug	Libracaine Dental (target)
Pain of injection score target	4 / 10 pain score	25% less pain on injection	3 / 10 pain score
Pulpal anesthesia onset time target	6.4 min. average	75% less time to anesthesia	1.5 min. average
Inflamed tissue reliability target	43% failure rate	33% lower failure rate	29% failure rate
Dosage Form	Injection solution	No Change	Injection solution
Administration Route	Subcutaneous injection	No Change	Subcutaneous injection
Conditions of Use	Dental clinicians in clinical setting	No Change	Dental clinicians in clinical setting
Anesthetic API	Lidocaine 2% (20 mg/ml)	No Change	Lidocaine 2% (20 mg/ml)
Vasoconstrictor API	Epinephrine 0.001% (0.01 mg/ml)	No Change	Epinephrine 0.001% (0.01 mg/ml)
Excipient	Potassium metabisulfite 1.2 mg/ml	No Change	Potassium metabisulfite 1.2 mg/ml
Excipient	Edetate disodium 0.25 mg/ml	No Change	Edetate disodium 0.25 mg/ml
Excipient	Sodium Chloride 6.5 mg/ml	-6.5 mg/ml	Sodium Chloride 0.0 mg/ml
Excipient Buffer	None (HCl titration to pH target)	+ 7.0 mg/ml	Sodium bicarbonate 7.0 mg/ml (0.7%)
Labeling	See reference drug label details	Very slight change anticipated	See reference drug label details
Primary packaging	1.7ml single chamber dental cartridge	1.7 ml dual chamber dental cartridge	1.7ml dual chamber dental cartridge
Secondary packaging	10-unit plastic blister pack	Eliminates unnecessary part & process	None
Shipping package	Thin cardboard shipping box - 50 units	Secondary seal, no piston movement	Sealed metal canister – 50 units
Storage pH target (range)	pH 4.0 (3.5 - 4.5)	No Change	pH 4.0 (3.5 - 4.5)
Delivered pH target (range)	pH 4.0 (3.0 - 4.5)	+ ~3.00 to pH 7.00 target	pH 7.00 (6.nn - 7.nn)
Storage osmolality target	365 mOsm/kg	- 206 mOsm/kg	159 mOsm/kg
Delivered osmolality target	365 mOsm/kg	-65 mOsm/kg	300 mOsm/kg

Balanced Pharma – Intellectual Property Summary



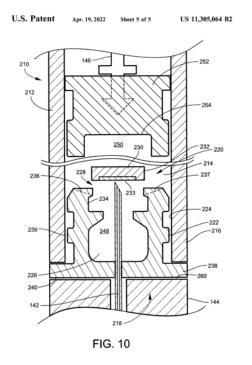
Pending – All Jurisdictions

BPI owns the following granted patents and pending patent applications:

- **U.S. Patent** No. 11,305,064 (issue date April 19th, 2022)
 - Expiration and LOE: 04 October 2038
- **U.S. Patent** No. 11,554,218 (issue date January 17th, 2023)
 - Expiration and LOE: 02 January 2038
- Canadian Application No. 3,111,347 (Canadian National Phase of PCT/IB2018/052598)
- European Application No. 18897951.2 (European Regional Phase of PCT/IB2018/052598)
- Japanese Application No. 2020-556351 (Japanese National Phase of PCT/IB2018/052598)
- Korean Application No. 10-2020-7021685 (Republic of Korea National Phase of PCT/IB2018/052598)
- **U.S. Application** No. 17/682,846
- U.S. Application No. 63/486,085 (provisional)
 - Expiration and LOE: Q1 2044

BPI also owns one U.S. registered trademark, for LIBRACAINER

BPI is represented by Greg Carlin, Esq., a partner at the Atlanta, Georgia IP law firm of Meunier, Carlin, & Curfman



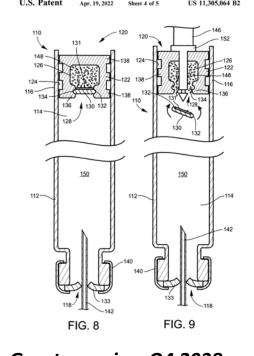
U.S. Grant – expires Q1 2038 **Pending – Other Jurisdictions**

Dental

Aesthetic

Podiatry

Urology



U.S. Grant – expires Q4 2038 **Pending – Other Jurisdictions**

Aesthetic Dental Aesthetic **Dermatological Surgery Dermatological Surgery Dermatological Surgery Emergency Medicine Emergency Medicine Emergency Medicine ENT Surgery Interventional Radiology ENT Surgery ENT Surgery** Interventional Radiology Interventional Radiology **Plastic Surgery Plastic Surgery Plastic Surgery Podiatry** Podiatry **Urology**

Urology

Neutral pH: Faster, Less Painful, More Reliable



Peer-Reviewed Clinical Research & Meta-analyses – Buffered Anesthetic in Dentistry

1. 2018 Meta-Analysis: Significantly Decreased Onset Time and Injection Pain

Guo et al from University of Southern California School of Dentistry concluded: "Buffered lidocaine significantly decreased onset time and injection pain (VAS) compared with non-buffered lidocaine in inferior alveolar nerve block."

2. 2017 Clinical Study: Reduces the Pain on Injection

Phero et al from University of North Carolina School of Dentistry concluded: "Buffered lidocaine reduces the pain on injection with a maxillary field block and results in similar lengths of pulpal anesthesia as non-buffered 2% lidocaine."

3. 2017 Clinical Study: Lower Pain on Injections

Warren et al from University of North Carolina School of Dentistry concluded: "After mandibular nerve block, Buffered 1% lidocaine can produce similar duration of pulpal anesthesia as non-buffered 2% lidocaine and lower pain on injections."

4. 2019 Meta-analysis: 2.29 Times More Reliable in Inflamed Teeth

Kattan et al from University of Pennsylvania School of Dentistry concluded: "Buffered local anesthetics have 2.29 times greater likelihood of achieving successful anesthesia [in pulpally involved teeth]."

Malamed – Handbook of Local Anesthesia, 7th Edition:

"Buffering local anesthetic cartridges benefits both dentists and their patients if the benefits of buffering are consistently reliable and if buffering is available in a system that incorporates the standard dental anesthetic cartridge."

"This author is an advocate for the use of buffered local anesthetics in all dental injections, particularly those in the mandibular arch."

Dr. Malamed is a leading authority on dental anesthesia, and has authored more than 140 scientific papers and 17 chapters in various medical and dental journals and textbooks in the areas of physical evaluation, emergency medicine, local anesthesia, sedation and general anesthesia.

Dr. Malamed has no affiliation with or financial interest in Balanced Pharma



Less painful = More referrals, less marketing expense, more income





Patients want a less painful dental injection, both for themselves and their children

58% of patients believe the injection is the worst part of the dental experience¹ 86% of patients stated a desire for a less painful dental injection¹



For dentists, a less painful injection means more referrals, less marketing expense and more income

56% of dentists stated a need for a less painful dental injection in their practice²



Research shows that pH-balanced anesthetics are less painful when injected

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Faster-acting = Shorter visits for patients, more time for dentists, more income





Patients want less time in the dental chair, both for themselves and their children

87% of patients expressed a desire for a faster-acting dental anesthetic with less wait time in the dental chair 100% of parents expressed a desire for a faster-acting dental anesthetic with less wait time in the dental chair for their children¹



For dentists, a faster-acting injection increases practice efficiency, revenue and income

56% of dentists state a need for a faster-acting anesthetic²
Dentists report an average delay of 5.9 minutes with current anesthetics²
Dentists report that anesthetic delays are responsible for running late 19% of the time²



Research shows that pH-balanced injections are faster-acting

2018 Meta-Analysis: <u>Significantly Decreased Onset Time and Injection Pain</u>
Guo et al from University of Southern California School of Dentistry concluded: "Buffered lidocaine significantly decreased onset time and injection pain (VAS) compared with non-buffered lidocaine in inferior alveolar nerve block.

2013 Clinical Study: Significantly reduces anesthetic onset time

Malamed, Tavana & Falkel concluded: "Alkalinizing lidocaine with epinephrine toward physiologic pH immediately before injection significantly reduces anesthetic onset time..."

¹Olson Research Group, "US Patient Dental Care Study Quantitative Report, May 7, 2021" N=140; ²Olson Research Group, "US Dentist Quantitative Report, August 13, 2021" N=181.

More reliable anesthesia = Happier patients, time saved for dentists, more income





Patients want to know the anesthetic will work, for themselves and their children

69% of patients said that being more likely to get their tooth numb before the procedure starts is a significant benefit of an anesthetic 1

26% of patients said that they had to get extra injections after anesthetic failure¹



Dentists want an anesthetic that is reliable, even in the presence of inflammation

47% of dentists state a need for a more reliable anesthetic² Dentists report a failure rate of 20% for current anesthetics²



Research shows that pH-balanced injections are more reliable

2019 Meta-analysis: <u>2.29 Times More Reliable in Inflamed Teeth</u>
Kattan et al from University of Pennsylvania School of Dentistry concluded: "Buffered local anesthetics have 2.29 times greater likelihood of achieving successful anesthesia [in pulpally involved teeth]."

Example ROI for GP dentists (time savings only, does not include marketing advantage)



Assumptions:

- 60-minute restorative visit
- 2 cartridges per procedure; 5 procedures per day
- 3-minute average time savings per procedure
- 200 working days per year, \$800,000 annual revenue

	Current SOC products (annual)	Libracaine® Dental (annual)	Net Change (annual)
Operating time	1,000 hours	1,000 hours	0
Number of procedures (recapture 3-minute time savings)	1,000	1,052	+52
Revenue (adjusted for 3-minute time savings)	\$800,000	\$841,600	+\$41,600
Anesthetic Cost (2 cartridges @ \$0.84/\$4.00 ARSP)	-\$1,680	-\$8,416	-\$6,736
Net Revenue (after anesthetic costs)	\$798,320	\$833,184	+\$34,864
ROI (not incl. marketing advantage)			5.2x