

1-A

FORM 1-A Offering Statement under Regulation A for Gastrodyne, Inc.

UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549



REGULATION A OFFERING STATEMENT  
UNDER THE SECURITIES ACT OF 1933

Received SEC  
SEP 17 2014  
Washington, DC 20549

Gastrodyne, Inc.  
(Exact name of Issuer as specified in its Charter)

Nevada  
(State Or Other Jurisdiction Of  
Incorporation Or Organization)

33-0196206  
(IRS Employer  
Identification No.)

5 Holland, Bldg. 223  
Irvine, Ca 92618  
(Address Of Principal Executive Offices)

Marvin P. Loeb, Chairman  
And Chief Executive Officer  
Gastrodyne, Inc.  
5 Holland, Bldg. 223  
Irvine, CA 92618

(Name And Address Of Agent For Service)

5900  
Industrial Classification No.

1-949-951-3800, Ext. 222  
(Telephone Number, Including Area Code, Of Agent For Service)

COPY TO:  
Allen C. Ostergar, III, Esq.  
Ostergar Law Group, P.C.  
27101 Puerta Real, Suite 450  
Mission Viejo, CA 92691

THIS OFFERING STATEMENT SHALL BE QUALIFIED BY OPERATION OF THE TERMS OF  
REGULATION A. NO PRELIMINARY (RED HERRING) OFFERING STATEMENTS WILL BE  
CIRCULATED TO THE PUBLIC. THE OFFERING STATEMENT WILL BE CIRCULATED TO  
THE PUBLIC ONLY AFTER IT IS QUALIFIED BY THE OPERATION OF REGULATION A.

(i)

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box: .

If the registrant elects to deliver its annual report to security holders, or a complete and legal facsimile thereof, pursuant to Item 11(a) (1) of this Form, check the following box: .

**CALCULATION OF REGISTRATION FEE**

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Title of Securities To Be Registered	Amount To Be Registered	Offering Price Per Share (1)	Aggregate Offering Price (1)	Amount of Registration Fee
Shares of Common Stock (\$0.001 Par Value)	5,000,000	\$1.00	\$5,000,000	\$ 0

(1) For the purpose of calculating the registration Fee.

**PLEASE INSERT BOTH DATES WHEN RECEIVED**

Date of filing the Form 1-A Offering Statement: \_\_\_\_\_, 2014.

Date of commencement of proposed sale to the public: \_\_\_\_\_, 2014.

(ii)

**GASTRODYNE, INC.**  
**Form 1-A Offering Statement**

**PART 1**

PART 1 – NOTIFICATION

ITEM 1. Significant Parties

The Issuer's officers and directors are as follows:

List the full names and business and residential address, as applicable, for the following persons:

(a) The Issuer's Directors:

Name

Marvin P. Loeb, Chairman & CEO

Business Address

5 Holland, Bldg. 223  
Irvine, CA 92618

Residence

5567-A Via Portora  
Laguna Woods, CA 92637

Glenn D. Yeik, President, COO & Director

Business Address

5 Holland, Bldg. 223  
Irvine, CA 92618

Residence

21831 Eagle Lake Circle  
Lake Forest, CA 92630

Donald Baker, Director

Business Address

544 Earliston Road  
Kenilworth, IL 60043

Residence

544 Earliston Road  
Kenilworth, IL 60043

(b) The Issuer's Officers:

Marvin P. Loeb, Chairman & CEO

Business Address

5 Holland, Bldg. 223  
Irvine, CA 92618

Residence

5567-A Via Portora  
Laguna Woods, CA 92637

Glenn D. Yeik, President, COO & Director

Business Address

5 Holland, Bldg. 223  
Irvine, CA 92618

Residence

21831 Eagle Lake Circle  
Lake Forest, CA 92630

Alan E. Loeb, Secretary & Treasurer

Business Address

5567-A Via Portora  
Irvine, CA 92618

Residence

5567-A Portora  
Laguna Woods, CA 92637

I-(ii)

(c) The Issuer's General Partner:

Not applicable. The Issuer is not a partnership and there is no general partner.

(d) Record owners of 5 percent or more of any class of the Issuer's equity securities:

The following are of record and beneficial owners of 5% or more of the Issuer's shares of \$0.01 per value common stock (the "Shares") issued and outstanding at the time of filing, the number of shares and the percent of the outstanding:

	<u>Shares Held</u>	<u>Percent of Outstanding</u>
Marvin P. Loeb Research Foundation, Inc. <sup>1</sup>	7,000,000	70%
Trimedyne, Inc.	3,000,000	30%

<sup>1</sup> A non-profit de jure Nevada corporation in the process of qualification as a 501(c) 4 charitable organization.

(e) Beneficial owners of 5 percent or more of any class of the Issuer's equity securities:

None, other than the parties listed in (d) above.

(f) Promoters of the Issuer:

The promoter of the issuer is:

Marvin P. Loeb, Chairman & CEO of the Issuer

(g) Affiliates of the Issuer.

Not Applicable. There are none.

(h) Counsel to the Issuer with respect to the proposed offering:

Allen C. Ostergar, III, Esq.  
Ostergar Law Group, P.C.  
27101 Puerta Real, Suite 450  
Mission Viejo, CA 92691

- (i) Each underwriter with respect to the proposed offering:  
Not Applicable. There are none.
- (j) The underwriter's directors:  
Not Applicable.
- (k) The underwriter's officers:  
Not Applicable.
- (l) The underwriter's general partner:  
Not Applicable.
- (m) Counsel to the underwriter:  
Not Applicable.

**ITEM 2. Application of Rule 262**

State whether any of the persons identified in response to Item 1 are subject to any of the disqualification provisions set forth in Rule 262.

- (a) Not Applicable. None of the above persons or parties are subject to any of the disqualifications set forth in Rule 262.
- (b) Not applicable.

**ITEM 3. Affiliate Sales**

Not applicable. No public resale of any outstanding securities of the Issuer held by affiliates included in this Form 1-A Offering Statement will be permitted for one year from the Termination Date of this Offering, and the Certificates for their Shares will bear a legend to this effect.

**ITEM 4. Jurisdictions in which securities are to be offered.**

- (a) The securities are to be offered by the Issuer and any broker/dealers who are member firms of FINRA and enter into Selling Dealer Agreements with the Issuer, if any, and their salespersons, if any.
- (b) The Offering will be made by coordination in the states whose Blue Sky laws permit registration of securities registered for sale with the Commission by coordination and in such other states as may be requested by broker/dealers who enter into a Selling Dealer Agreement with the Issuer, if any.

**ITEM 5. Unregistered Securities Issued and Sold Within One Year.**

- (a) The following unregistered securities of the Issuer were issued and/or sold within one year prior to filing of this Form 1-A Offering Statement.

- (1) Name of Issuer: Gastrodyne, Inc., a Nevada corporation.
- (2) Title and Amount of Securities Issued:
  - a. 7,000,000 Shares of Common Stock (\$0.001) par value (the "Shares") were issued to the Marvin P. Loeb Research Foundation, Inc. at no cost in a private transaction on September 3, 2014, in consideration of the services of Marvin P. Loeb, the Issuer's Chairman and CEO, in the planning and organization of the Issuer, the development of its products, conceiving its marketing plan and clinical trial program and assembling its management from May 13, 2012 to August 31, 2014.
  - b. 3,000,000 Shares were sold in a private transaction on September 3, 2014, to Trimedyne, Inc. ("Trimedyne") at a price of \$0.01 per Share in consideration of Trimedyne's entering into a 20 Year Exclusive, Worldwide, Renewable, Private Label & Distribution Agreement (the "Private Label Agreement") with the Issuer, under which Trimedyne agreed to (a) sell its lasers and fiber-optic devices to the Issuer under the Issuer's label at Trimedyne's GAAP Cost plus 35% and, subject to the Issuer's raising at least \$2.5 million within one year from the date of the Private Label Agreement, to conduct clinical trials of Trimedyne's lasers and fiber-optic devices in the treatment of Type II Diabetes, Obesity and GERD (the "Conditions"), as described in the Offering Circular, and (b) if the Issuer obtains FDA clearance or approval and Medicare reimbursement approval for at least one or more of the Conditions (the "Approved Conditions"), Trimedyne shall grant the Issuer the exclusive, worldwide right to distribute Trimedyne's lasers and fiber-optic devices for use in the treatment of the Approved Conditions throughout the Term of the Private Label Agreement.
- (3) Aggregate offering price and basis of Compensation:
  - a. None. No compensation was paid.
  - b. \$30,000. No compensation was paid.
- (b) Sales of unregistered securities.

See (2) a and b above.
- (c) Indicate the section of Securities Act or Commission rule or regulation relied upon for exemption from registration requirements.

I-(v)

- (1) The above issuance and/or sales of securities were made pursuant to Section 4(2) of the Securities Act of 1933, as amended, as transactions not involving a public offering, and the Shares are “restricted” pursuant to Rule 144.
- (2) None of the officers, directors or principal securities holders of the Issuer have sold any securities of the Issuer within the twelve (12) months prior to filing of this Form 1-A Offering Statement.

ITEM 6. Other Present or Proposed Offerings

If permissible, the Issuer plans to offer privately, pursuant to Regulation D of the Securities Act of 1933, as amended, shares of its \$0.001 par value common stock (the “Shares”) solely to Accredited Investors in those States whose Blue Sky Laws do not permit registration of this Offering Statement under Regulation A by conformance. Please advise us if this is not permissible. If not permissible, we will not offer any Shares privately pursuant to Regulation D until after the Termination Date of this Offering.

ITEM 7. Marketing Arrangements

- (a) Not Applicable. There are presently no marketing arrangements in place with any underwriter or broker/dealers.
- (b) Not Applicable. There are presently no marketing arrangements in place with any underwriter or broker/dealers.

ITEM 8. Relationship with Issuer of Experts Named in the Offering Statement.

Not Applicable, other than Allen C. Ostergar, III, Esq., acting as Counsel for the Issuer.

ITEM 9. Use of a Solicitation of Interest Document.

Not Applicable. No preliminary (red-herring) Offering Circulars, written documents or broadcast scripts were used prior to the filing of this Form 1-A Registration Statement. Only the qualified (final) Offering Circular will be used after the Form 1-A Offering Statement is qualified by the operation of Regulation A.

GASTRODYNE, INC.

CROSS REFERENCE SHEET

<u>Item in Form 1-A Offering Statement</u>	<u>Location in Offering Circular</u>
1. Cover Page of Offering Circular	Cover Page of Offering Circular
2. Distribution Spread	Cover Page of Offering Circular
3. Summary Information, Risk Factors and Dilution	Summary; Risk Factors; Dilution
4. Plan of Distribution	The Offering
5. Use of Proceeds by Issuer	Use of Proceeds
6. Description of Business	The Issuer and Business
7. Description of property	Business
8. Directors, Executive Officers and Significant Employees	Management
9. Remuneration of Directors and Officers	Management
10. Security Ownership of Management and and Certain Security Holders	Security Ownership of Management and Certain Control Holders
11. Interest of Management and Others in Certain Management Transactions	Transactions with Management
12. Securities Being Offered	The Offering and Description of Securities

**GASTRODYNE, INC.**  
**Form 1-A Offering Statement**

**PART II**  
**OFFERING CIRCULAR**

PART II  
**OFFERING CIRCULAR**  
**GASTRODYNE, INC.**

**\$5,000,000**

**5,000,000 SHARES OF COMMON STOCK  
AT A PRICE OF \$1.00 PER SHARE**

The Date of Filing of This Offering Circular is \_\_\_\_\_, 2014.

**THE OFFERING STATEMENT, OF WHICH THIS OFFERING CIRCULAR IS A PART, SHALL BECOME QUALIFIED ON THE 20TH DAY FOLLOWING THE DATE OF ITS FILING WITH THE SECURITIES & EXCHANGE COMMISSION BY THE OPERATION OF REGULATION A.**

The Date of Commencement of Sales of Shares to the Public is \_\_\_\_\_, 2014.

**The Offering**

**GASTRODYNE, INC.**, a Nevada corporation (hereinafter referred to as the "Company", "we", "our" or "us") is offering up to 5,000,000 shares of its \$0.001 par value common stock (the "Shares") to the public at a price of \$1.00 per Share for an aggregate of \$5,000,000, if all of the Shares being offered are sold, under a Form 1A Offering Statement, (comparable to a "Registration Statement") pursuant to Regulation A of the Securities and Exchange Commission. The minimum purchase in this Offering is 25,000 Shares for \$25,000.

We presently have 10 million Shares outstanding. If all of the 5,000,000 Shares being offered are sold, we will have 15 million Shares outstanding, and the investors in this Offering will own 33.3% of the Shares of the Company then outstanding (See "CAPITLIZATION" and "DILUTION").

This Offering is being made on a "best efforts" basis by the Company pursuant to Section 3(b) of the Securities Act of 1933, as amended (the "Act") through certain of the officers or directors of the Company and such broker/dealers who (a) are member firms of the Financial Industry Regulatory Association ("FINRA") and (b) enter into Selling Dealer Agreements with the Company, (the "Selling Dealers").

We are presently privately held, and there is presently no public trading market for our Shares. Although the Shares sold pursuant to this Offering Circular, when issued, will be fully paid, non-assessable and freely tradable, without any legend restricting transfers, we cannot assure that any public trading market in our Shares will arise. We plan to use the stock symbol "GDYN", if available, in the event a public trading market in our Shares arises. There is no underwriter of this Offering, and there is no assurance any or all of the Shares being offered will be sold. Subscriptions for Shares are subject to acceptance in whole or in part by the Company.

There is no minimum number of Shares that must be sold to complete this Offering. The funds received from Subscription for Shares accepted by the Company will not be deposited into an escrow account and will be immediately available for use by the Company

This Offering of Shares will terminate on the earlier to occur of (a) the sale of all of the 5,000,000 Shares being offered or (b) nine (9) months following the Date of Commencement of the sale of Shares, unless the Offering is terminated at an earlier date by the Company (the "Termination Date"). See "THE OFFERING & PLAN OF DISTRIBUTION" for complete terms of the Offering.

The following Table illustrates the price per Share, the Commission per Share payable to Selling Dealers, the Net Proceeds to the Company on a Per Share basis and the total Commissions and Net Proceeds From the Sales of Shares, assuming all of the Shares being offered are sold by Selling Dealers.

	Price to Public	Commissions	Net Proceeds To The Company
Per Share	\$1.00	\$0.10	\$0.90
Total	\$5,000,000	\$500,000	\$4,500,000 <sup>1</sup>

<sup>1</sup> Before legal, accounting and other selling expenses of the Offering, estimated at \$150,000.

To the extent a Subscription Agreement is accepted by the Company, the Subscriber will be mailed a stock certificate for the number of Shares accepted by the Company within fifteen (15) days of its acceptance. The subscriber will receive a check refunding any part of the Subscription not accepted by the Company, but without interest thereon, within said fifteen (15) day period.

Within one (1) month after the date of completion of this Offering, the Company will issue at no cost to the purchasers of Shares in this Offering, one (1) Shareholder Warrant for each Share purchased in the Offering. Each Shareholder Warrant may be exercised to purchase one (1) Share at a price of \$2.00 per Share at any time during a period of twenty-four (24) months, commencing twelve (12) months after the Termination Date of this Offering. The Shareholder Warrants contain no anti-dilution provisions and are redeemable by the Company on thirty (30) days prior written notice at a price of \$0.001 per Warrant, if the Shares trade at a price of least \$3.00 per Share for five (5) consecutive trading days during the exercise period of the Shareholder Warrants. The Shareholder Warrants are not transferrable by the party to whom they are issued, except by the laws of will and descent, and must be held in registered name.

Each Selling Dealer will be paid a commission of ten percent (10%) of the gross proceeds of the Shares sold by them in this Offering, if any. In addition, we will issue to each Selling Dealer at no cost Selling Dealer Warrants in an amount equal to ten percent (10%) of the number of Shares sold by each Selling Dealer in this Offering, if any. Each of the Selling Dealer Warrants is exercisable to purchase one (1) Share at a price of \$1.10 per Share during a period of two (2) years, commencing one (1) year following the Termination Date of this Offering. The Selling Dealer Warrants have no anti-dilution provisions, are redeemable by the Company on the same terms and conditions as the Shareholder Warrants, are not transferrable and must be held in registered name.

If any of the Selling Dealers exercise their Selling Dealer Warrants, in addition to one (1) Share of the Company, those Selling Dealers, if any, will be issued at no cost one (1) Additional Selling Dealer Warrant to purchase one Share of the Company at a price of \$2.00 per Share for each Selling Dealer Warrant exercised by them. The Additional Seller Dealer Warrants are exercisable on the same terms and conditions as the Shareholder Warrants, have no anti-dilution provisions, are redeemable by the Company on the same terms and conditions as the Shareholder Warrants, are not transferrable and must be held in registered name.

Certain officers or directors of the Company who recruit Selling Dealers for the Company, in addition to any other compensation, will receive cash compensation of two percent (2%) of the gross proceeds to the Company from the sale of Shares of the Company by the Selling Dealers recruited by each of them, if any, and they will be issued at no cost Selling Dealer Warrants and Additional Selling Dealer Warrants in an amount equal to 20% of the number of such Warrants issued to the Selling Dealers they each recruit, if any. The Selling Dealer Warrants and Additional Selling Dealer Warrants issued to officers or directors of the Company are exercisable and redeemable by the Company on the same terms and conditions as the Shareholder Warrants, have no anti-dilution provisions, are not transferrable and must be held in registered name.

The 5,000,000 Shares being offered to the public in this Offering, the 10,000,000 Shares presently outstanding, the 5,000,000 Shares issuable upon exercise of the Shareholder Warrants, the 600,000 Shares issuable upon exercise of the Selling Dealer Warrants and the 600,000 Shares issuable upon exercise of the Additional Selling Dealer Warrants, including any which are issued to officers or directors of the Company, assuming all of the Shares being offered are sold, are being registered in the Registration Statement of which this Offering Circular is a part, but the Shareholder Warrants, the Selling Dealer Warrants and the Additional Selling Dealer Warrants are not being so registered. As a result, no market for any of these Warrants is expected to arise.

The Shares being offered to the public and Shares purchased by the exercise of the Shareholder Warrants, when exercisable as described above, can be sold publicly if a trading market for our Shares arises, which cannot be assured. However, none of the presently outstanding Shares and none of the Shares issuable upon the exercise of the Selling Dealer Warrants or the Additional Selling Dealer Warrants can be sold publicly until after one (1) year from the Termination Date of this Offering. If the holder of any of such Warrants is an officer or director of the Company or the owner of 5% or more of the Company's Shares, the Shares purchased by the exercise of such Warrants may be sold publicly after one (1) year from the Termination Date of this

Offering, subject to certain holding periods and volume limitations. (See "THE OFFERING & PLAN OF DISTRIBUTION".)

**THESE SECURITIES ARE SPECULATIVE AND INVOLVE A HIGH DEGREE OF RISK. SEE "RISK FACTORS."**

**INVESTMENT IN SMALL BUSINESSES INVOLVES A HIGH DEGREE OF RISK, AND INVESTORS SHOULD NOT INVEST ANY FUNDS IN THIS OFFERING UNLESS THEY CAN AFFORD TO LOSE THEIR ENTIRE INVESTMENT. SEE THE RISK FACTORS THAT MANAGEMENT BELIEVES PRESENT THE MOST SUBSTANTIAL RISKS TO AN INVESTOR IN THIS OFFERING.**

**IN MAKING AN INVESTMENT DECISION, INVESTORS MUST RELY UPON THEIR OWN EXAMINATION OF THE ISSUER AND THE TERMS OF THE OFFERING, INCLUDING THE MERITS AND RISKS INVOLVED. THESE SECURITIES HAVE NOT BEEN RECOMMENDED OR APPROVED BY ANY FEDERAL OR STATE SECURITIES COMMISSION OR REGULATORY AUTHORITY. FURTHERMORE, THESE AUTHORITIES HAVE NOT PASSED UPON THE ACCURACY OR ADEQUACY OF THIS OFFERING CIRCULAR. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.**

**THE U.S. SECURITIES AND EXCHANGE COMMISSION DOES NOT PASS UPON THE MERITS OF OR GIVE ITS APPROVAL TO ANY OF THE SECURITIES BEING OFFERED OR THE TERMS OF THE OFFERING, NOR DOES IT PASS UPON THE ACCURACY OR COMPLETENESS OF ANY OFFERING CIRCULAR OR OTHER SELLING LITERATURE. THESE SECURITIES ARE OFFERED UNDER AN EXEMPTION FROM REGISTRATION. HOWEVER, THE COMMISSION HAS NOT MADE AN INDEPENDENT DETERMINATION THAT THESE SECURITIES ARE EXEMPT FROM REGISTRATION.**

**THIS OFFERING CIRCULAR CONTAINS ALL OF THE REPRESENTATIONS BY THE COMPANY CONCERNING THIS OFFERING AS OF THE FILING DATE OF THE OFFERING CIRCULAR, AND NO PERSON SHALL MAKE DIFFERENT OR BROADER STATEMENTS THAN THOSE CONTAINED HEREIN. INVESTORS ARE CAUTIONED NOT TO RELY UPON ANY INFORMATION NOT EXPRESSLY SET FORTH IN THIS OFFERING CIRCULAR.**

We plan to furnish annual reports to our shareholders, which may include audited or un-audited annual financial statements, or we may post them on our website, [www.Gastrodyne.com](http://www.Gastrodyne.com). We may also provide un-audited quarterly financial statements and periodic progress reports to shareholders or post them on our website. We are presently not a reporting company ("Reporting Company") under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). However, we intend to become a Reporting Company, if and when feasible, if a trading market in our Shares arises, although this occurring or continuing cannot be assured.

## **TABLE OF CONTENTS**

<b><u>TOPIC</u></b>	<b><u>PAGE NO.</u></b>
OFFERING CIRCULAR	1
The Offering	1
SUMMARY (No Subheadings of the Summary Are Listed herein)	5
RISK FACTORS	10
FORWARD-LOOKING STATEMENTS	15
CAPITALIZATION	15
DILUTION	15
USE OF PROCEEDS	16
THE OFFERING & PLAN OF DISTRIBUTION	17
MANAGEMENT'S DISCUSSION	19
BUSINESS	21
General	21
Malfunctioning Nerves Cause Arrhythmia, Asthma and Joint Pain	22
Loose Valves Cause GERD, Heart Valve Leakage and Incontinence	22
Clinical Trial Management	23
The Conduct of Our Clinical Trials	24
Pre-Clinical Trial Testing	24

<u>TOPIC</u>	<u>PAGE NO.</u>
Our Randomized Controlled Clinical Trials	24
Our Gastroscopic Procedures	25
Our Laparoscopic Procedure	26
Potential Market Sizes	27
Possible Acquisition of the Company	28
Marketing Plan	28
Marketing Strategy	29
The Private Label Agreement	29
Field Service	30
Management	31
Board of Directors	31
Trimedyne's Intellectual Property	32
Incentive Stock Purchase Plan	32
Stock Option Plan	33
<b>REGULATORY REQUIREMENTS</b>	33
Government Regulation	33
Investigational Device Exemption	33
510(k) Premarket Notification	34
Premarket Approval (PMA)	34
Inspection of Plants	34
State Regulation	34
Cost of Compliance With FDA and Other Applicable Regulations	35
<b>REIMBURSEMENT</b>	35
<b>OTHER MATTERS</b>	35
Employees	35
Competition	35
Insurance	35
Retirement Plans	36
Properties	36
Litigation	36
Executive Compensation	36
Security Ownership of Management and Others	36
Miscellaneous	37
<b>TRANSACTIONS WITH MANAGEMENT</b>	37
<b>DESCRIPTION OF SECURITIES</b>	37
Common Stock	37
Warrants	38
Anti-Dilution Rights	38
Reports to Shareholders	38
Transfer Agent	38
<b>THE COMMISSION'S POLICY ON INDEMNIFICATION</b>	38
<b>SHARES AVAILABLE FOR FUTURE SALE</b>	39
<b>TAX CONSEQUENCES</b>	39
<b>LEGAL MATTERS</b>	39
<b>AVAILABLE INFORMATION</b>	39
<b>FINANCIAL STATEMENTS</b>	40
Balance Sheet (Unaudited)	40
Profit and Loss Statement (Unaudited)	41
Cash Flow Statement (Unaudited)	41

## SUMMARY

The following Summary is qualified in its entirety by the more detailed information and the financial statements appearing elsewhere in this Offering Circular.

### **The Company**

Gastrodyne, Inc. (the "Company". "we", "our" or "us") was incorporated under the laws of the State of Nevada on August 28, 2014. Our office is located at 5 Holland, Suite A, Bldg. 223, Irvine, CA 92618. Our telephone number is 1-949-951-3800, Ext. 233, our toll free telephone number is 1-800-733-5273, Ext. 233 and we expect our website will be [www.gastrodyne.com](http://www.gastrodyne.com). We were only recently incorporated, we are an early development stage, emerging growth company, and we presently have no business or operations.

The Company was organized by Marvin P. Loeb, Sc.D. ("Dr. Loeb"), a serial entrepreneur who founded 27 companies in the healthcare and related fields over a period of forty years, two of which reached market capitalizations of about \$1.6 and \$1.0 billion each. Dr. Loeb formed the Company to finance and conduct at least four (4), 10 patient "pilot" clinical trials and, based on the results of such "pilot" clinical trials, up to four (4), 100 or more patient, randomized, controlled clinical trials of a proprietary Holmium laser ("Laser") and patented and patent pending side firing fibers ("Fibers"), developed and manufactured by Trimedyn, Inc. ("Trimedyn"), a 34 year old, publicly-held manufacturer of high-tech medical lasers and optical fiber devices, of which Dr. Loeb is the founder, CEO and Chairman of the Board.

**The conditions to be treated in the above clinical trials are Type II Diabetes, Obesity and Gastro Esophageal Reflux Disease or "GERD", all in minimally-invasive, endoscopic (gastroscopic or laparoscopic), outpatient procedures, with only local anesthesia and sedation.**

Trimedyn has agreed to manufacture the Lasers and Fibers for the Company, under the Company's name and trademark, under a 20 Year, Renewable, Exclusive, Worldwide, Private Label & Distribution Agreement with the Company dated September 3, 2014 (the "Private Label Agreement"), at Trimedyn's GAAP Cost plus 35%, instead of its usual mark-up, which is typically higher.

Trimedyn has also granted the Company, under the Private Label Agreement, the exclusive, worldwide right to distribute its Lasers and Fibers for the treatment of (a) Type II Diabetes, (b) Obesity and (c) Gastro Esophageal Reflux Disease or "GERD", subject to the Company's raising at least \$2.5 million within one (1) year from the date of the Private Label Agreement, to finance the above clinical trials.

**The Holmium Laser and Side Firing Fibers manufactured by Trimedyn for the Company have been cleared for sale by the FDA for use in gastro-intestinal ("GI") surgery and in endoscopic (gastroscopic or laparoscopic) procedures for the vaporization, coagulation, incision and excision of tissues, respectively, called a "General Use FDA Clearance", are CE Marked for sale in the European Union and are registered for sale in many countries that require their own registration of medical devices, including Australia, Brazil, Canada, China, Indonesia, Korea, Taiwan and other countries, but not yet in Japan. Two of the medical centers in each of the Company's 100 or more patient, randomized, controlled clinical trials are expected to be in Japan, to commence the Ministry of Health approval and reimbursement process there.**

As a result of the above General Use FDA Clearance, no Investigational Device Exemption ("IDE") from the FDA is expected to be required. These clinical trials are expected to be conducted at up to ten (10) or more medical centers in the U.S. under Institutional Review Board ("IRB") approvals and at up to ten (10) or more medical centers outside the U.S. under Ethics Committee approvals. There is no assurance the FDA or foreign government authorities will not require regulatory filings by the Company that may delay the start of our clinical trials.

The follow-up periods of the Company's 100 or more patient, randomized, controlled clinical trials are expected to end at one (1), six (6) and twelve (12) months following the date of the patient's discharge from the medical center.

The use of the Company's Lasers and Side Firing Fibers specifically for the treatment of Type II Diabetes, Obesity or GERD is not presently cleared or approved for sale by the FDA and is not presently being reimbursed by Medicare or others specifically for the treatment of any of the above conditions. Before the Company can apply for: (a) clearance or approval of the FDA to sell its Lasers and Fibers specifically for the treatment of Type II Diabetes, Obesity or GERD, (b) the CE Mark or (c) reimbursement by Medicare and others for the use of its Lasers and Fibers specifically for the treatment of any of the above conditions, we must first complete clinical (human) trials that demonstrate their safety and therapeutic efficacy in the treatment of each of the above conditions, which can be costly and take a considerable period of time, with no assurance the outcome of any of such clinical trials will be successful. The FDA and foreign government authorities may require filings by the Company that will delay the start of our clinical trials. (See "REGULATORY REQUIREMENTS" and "REIMBURSEMENT".)

Dr. Loeb conceived the use of Holmium "pulsed" Lasers and Side Firing Fibers in the treatment of the above conditions, planned the clinical trials, recruited internationally respected physicians to lead the clinical trials, and developed a unique marketing strategy for the Company. Dr. Loeb filed two (2) U.S. Patent Applications covering the Laser and Fibers and other sources of focused thermal energy for (a) denervating nerves to treat Type II Diabetes and other conditions, and (b) shrinking sphincter muscles of valves to treat Obesity and GERD and other conditions, which he assigned to Trimedynе without royalty. In consideration of Dr. Loeb's founding the Company and the above contributions, the Company privately issued for investment, without cost, seven (7) million of its Shares to the Marvin P. Loeb Research Foundation, Inc. (the "Foundation"), a Nevada non-profit corporation. Dr. Loeb is the Chairman of the Foundation, but is not an owner or beneficiary of the Foundation. (See "Management" under 'BUSINESS'.)

In consideration of Trimedynе's entering into the Private Label Agreement with the Company on September 3, 2014, giving the Company the exclusive, worldwide right to distribute Trimedynе's proprietary Lasers and patented and patent pending Fibers, as well as improved versions of these devices, for the treatment of Type II Diabetes, Obesity and GERD, subject to the Company raising at least \$2,500,000 within one (1) year from the date of the Private label Agreement, and in consideration of Trimedynе's agreeing to manufacture the Lasers and Fibers for the Company at Trimedynе's GAAP Cost plus 35%, instead of its usual mark-up of 60% to 200%, the Company sold privately for investment three (3) million of its Shares to Trimedynе at a price of \$0.01 per Share.

See "Management" under "BUSINESS" for (a) Dr. Loeb's accomplishments and many contributions to medicine, (b) the experience and capabilities of the other officers and directors of the Company. See "The Private Label Agreement" under "BUSINESS" for information on its significant benefits to the Company. See "Clinical Trial Management" under 'BUSINESS" for the experience of Professors Kahrilas and Pandolfino, who are the past and present Chairman of the Department of Gastroenterology of the Feinberg School of Medicine of Northwestern University in Chicago, are among the world's leading experts in the treatment of GERD and other gastroenterological conditions and have agreed to serve as the Co-Principal Investigators of the Company's clinical trials.

### **Malfunctioning Nerves Cause Asthma, Cardiac Arrhythmia and Joint Pain**

The body's sympathetic and parasympathetic nerves ("S/PS Nerves") have been shown to malfunction and send false messages to the brain, causing or contributing to Hypertension, Asthma, Cardiac Arrhythmia, Spinal Joint Pain and other conditions to occur. Dr. Loeb believes denervating (coagulating) and interrupting a sufficient amount of the malfunctioning S/PS Nerves of the intestines, where they pass through the duodenum or within the outer layer of or on the exterior of the celiac artery, on their way to the brain, may stop the transmission of these false nerve messages to the brain and treat or at least partially relieve Type II Diabetes.

**In persons suffering from Type II Diabetes, their body makes insulin, but it cannot be properly absorbed in their intestines. Dr. Loeb believes malfunctioning S/PS Nerves of the intestines may cause Type II Diabetes by sending false messages to the brain that the body's insulin is a foreign substance, causing the brain to activate the immune system to destroy or alter it and instructing glands to produce enzymes to decompose it, so it will not activate receptors in the intestines permitting its absorption. Type II Diabetes is also known as "insulin absorption resistance".**

In at least two (2) of the Company's four (4) or more 10 patient "pilot" clinical trials and its two (2), 100 or more patient clinical trials to treat Type II Diabetes, we will denervate (coagulate) these malfunctioning S/PS Nerves (a) in the wall of the duodenum in a gastroscopic procedure from inside the duodenum and (b) in the outer layer and on the exterior of the celiac artery, where the celiac artery exits the duodenum, in a laparoscopic procedure from outside the celiac artery, to determine which procedure produces the best clinical results.

**Trimedyne's Holmium Lasers and Side Firing Fibers have been successfully used for more than 18 years, since 1996, to denervate malfunctioning S/PS Nerves of spinal joints to treat severe back pain.**

Trimedyne has been assigned by Dr. Loeb a U.S. Patent Application, without royalty, covering its Laser and Fibers and other sources of thermal energy to denervate malfunctioning nerves to treat Type II Diabetes and a number of other conditions. The issuance of a U.S. Patent from Trimedyne's pending U.S. Patent Application cannot be assured.

If not fully coagulated, malfunctioning S/PS Nerves can regenerate, grow back together and resume sending false messages to the brain. We believe directly denervating (coagulating) a sufficient volume of these malfunctioning S/PS Nerves under direct vision in gastroscopic or laparoscopic, outpatient procedures, can create a gap sufficiently large to prevent their growing back together and can treat or at least substantially reduce the adverse effects of Type II Diabetes, although our accomplishing this cannot be assured.

### **Loose Valves Cause GERD, Incontinence and Leakage from Heart Valves**

Loose sphincters of valves occur in humans and have been shown to cause Gastro Esophageal Reflux Disease or "GERD" by allowing stomach acids to leak through a loose esophageal valve and erode the sensitive inner lining of the esophagus, leakage of blood from loose heart valves is known to occur, urinary incontinence by leakage of urine through a loose urethral valve, fecal incontinence by leakage of fecal matter through a loose anal valve and other conditions.

**Dr. Loeb believes, if a person is born with a loose pyloric valve at the bottom of the stomach, or it becomes loose over time, partially digested food continuously flows through the loose valve into the duodenum and intestines, the stomach is never full, the patient does not feel "full" and continues to eat, causing or contributing to Obesity.**

Holmium laser energy has the ability to photomechanically cross-link collagen, a constituent of all soft tissues of the body, causing it to promptly shrink by 10% or more when Holmium laser energy contacts the tissue. Dr. Loeb believes this laser shrinkage effect can be used to shrink and tighten the sphincter of the pyloric valve of the stomach to treat or partially relieve Obesity and to shrink and tighten the sphincter of the esophagus to treat or partially relieve GERD.

**Trimedyne's Holmium Laser and Side Firing Fibers have been used for 20 years, since 1994, to shrink tissues in Orthopedics, for example, the capsule of the shoulder in people who frequently dislocate their shoulder, and to shrink nucleus pulposa tissue of herniated "bulging" discs in the spine, by shrinking the bulge, which presses on nerves encircling the disc, causing severe pain.**

Trimedyne has been assigned by Dr. Loeb, a U.S. Patent Application, without royalty, covering its Laser and Fibers and other sources of thermal energy to shrink loose valves to treat Obesity, GERD and a number of other conditions. The issuance of a U.S. Patent from Trimedyne's pending U.S. Patent Application cannot be assured.

### **Clinical Trial Management**

Professor Peter J. Kahrilas, M.D., former Chairman of the Department of Gastroenterology, and Professor John E. Pandolfino, M.D., the present Chairman of the Department of Gastroenterology of the Feinberg School of Medicine of Northwestern University in Chicago, have agreed to be the Co-Principal Investigators of the Company's four or more, 10 patient "pilot" clinical trials and its four (4), 100 or more patient, randomized, controlled clinical trials. They will select and train investigators for the Company's clinical trials in the U.S., Canada and Mexico, select a Regional Chief Investigator for Central and South America, a Regional Chief Investigator for Europe and the Middle East and a Regional Chief Investigator for Eastern Europe, SE Asia and Asia, who will each select and train Investigators for our clinical trials in their respective areas.

Professors Kahrilas and Pandolfino will prepare the Protocols for the four, 10 patient “pilot” clinical trials and the four, 100 or more patient, randomized, controlled clinical trials, they will monitor the clinical trials and, when the clinical trials are completed, they will prepare papers on the results of the clinical trials for submission to a respected, peer reviewed, medical journal appropriate for the medical condition.

Professors Kahrilas and Pandolfino are among the world’s leading experts in gastroscopic procedures to treat GERD and the treatment of other gastroenterological conditions. (See “Clinical Trial Management” under ‘BUSINESS’ for additional information on Professors Kahrilas and Pandolfino.)

### **The Conduct of Our Clinical Trials**

All of the Company’s “pilot” and randomized, controlled clinical trials are expected to be conducted in the U.S. under Institutional Review Board (“IRB”) approvals and outside the U.S. under Ethics Committee approvals. All prospective subjects in the Company’s clinical trials must sign a Patient Informed Consent Form prior to enrollment or treatment in any of our clinical trials.

All of the patients enrolled in at least four (4) of the ten (10) patient “pilot” clinical trials and the four (4), 100 or more patient, randomized, controlled clinical trials (Laser Treated or Controls) are expected to receive optimal medical (drug) therapy during the “pilot” clinical trials and throughout the 100 or more patient, randomized, controlled clinical trials.

The follow-up periods of the Company’s four (4), 100 or more patient, randomized, controlled clinical trials are expected to end at one (1), six (6) and twelve (12) months following the date of the patient’s discharge from the medical center. The follow-up period of the “pilot” clinical trials are expected to end one (1) month after such discharge.

An independent data committee, selected by Professors Kahrilas and Pandolfino, will analyze the clinical trial data. The patients, the interviewers of the patients and the reviewers of the patient data will be blinded as to which procedure the patient received.

### **Pre-Clinical Trial Testing**

Prior to conducting any of the four (4) multi-center, 100 or more patient, randomized, controlled clinical trials, the Laser and Fibers will be tested in one or more 10 patient “pilot” clinical trials in the treatment of each of Type II Diabetes, Obesity and GERD outside the U.S., where such testing costs much less than in the U.S., under the direction of Professors Kahrilas and Pandolfino. If the first “pilot” clinical trial of a condition indicates the level of laser energy or the pulse repetition rate should be changed, another 10 patient “pilot” clinical trial will be conducted to confirm that the change properly treats the condition.

Another benefit of the “pilot” clinical trials is they may indicate which of the company’s four (4), 100 or more patient randomized, controlled clinical trials would be best to pursue. If, based on the results of the “pilot” clinical trials, any of their four larger clinical trials is deferred until the level of laser energy is changed or the Fiber is improved, it may enable the Company to increase the number of patients in the remaining clinical trials, which may enhance their credibility and the likelihood of their obtaining specific FDA clearance and specific Medicare reimbursement, which cannot be assured.

### **Our Randomized, Controlled Clinical Trials**

In each of the four (4), 100 or more patient, randomized, controlled clinical trials, at least 50 patients suffering from Type II Diabetes (2 clinical trials), Obesity or GERD (one clinical trial each), will be randomly assigned to a Laser Group, one for each of the four (4) clinical trials, and at least 50 patients suffering from one of the above conditions will be randomly assigned to a Control Group, one for each of the four (4) clinical trials.

The patients in the two Laser Groups in the two 100 or more patient clinical trials to treat Type II Diabetes will receive either a laser gastroscopic procedure to denervate malfunctioning S/PS Nerves in the wall of the duodenum from inside the duodenum, or a laser laparoscopic procedure to denervate malfunctioning S/PS Nerves in the outer layer and on the exterior of the celiac artery, where it exits the duodenum, from outside the celiac artery. In the Laser Groups of the two (2), 100 or more patient clinical trials to treat Obesity and GERD, the patients will receive a laser gastroscopic procedure to shrink the sphincter of their pyloric valve or the sphincter of their esophagus, from inside the pyloric valve or esophagus.

The patients in the Control Groups of each of the four (4), 100 or more patient clinical trials to treat Type II Diabetes, Obesity and GERD will receive a “sham” procedure, in which the patient will be positioned, the gastroscopie will be inserted and the Fiber will be extended from the gastroscopie and rotated and advanced, as described in “Our Gastroscopie Procedures” and “Our Laparoscopic Procedures” under “BUSINESS”, but no laser energy will be emitted. The gastroscopie or laparoscope may hereafter be referred to as the “Scope”.

**There is no assurance our Fibers or any modifications of these Fibers Trimedyne may make can be used successfully in our clinical trials or that our clinical trials using these Fibers will be successful.**

See “Our Gastroscopie Procedures” and “Our Laparoscopic Procedure” under ‘BUSINESS’ for detailed information on the Company’s four (4) procedures to treat Type II Diabetes, Obesity and GERD. See “Marketing Strategy” under “BUSINESS” for information on how we plan to supply our Lasers and repair and maintain them, free of charge, to customers who agree to purchase a specified number of our Fibers per month. See “Stock Option Plan” and “Incentive Stock Purchase Plan” under “BUSINESS” for information on these Plans.

### Potential Market Sizes

**Diabetes** affects an estimated 26 million people in the U.S., of which about 23.4 million have Type II Diabetes. Another 79 million Americans have pre-diabetes which, over time, often progresses to Type II Diabetes. According to the U.S. Centers for Disease Control (“CDC”), the treatment of Diabetes and its adverse effects, which include heart attacks, congestive heart failure, peripheral artery disease, amputations, hypertension, kidney failure and blindness, costs \$174 billion each year in the U.S. **About ten percent of all U.S. healthcare dollars is spent on treating Diabetes and its adverse effects.**

**Obesity** affects millions of people in the U.S. According to the American Heart Association (“AHA”), 154.7 million people in the U.S. are overweight or obese, of which 78.4 million are obese. The cost of being overweight or obese is estimated at \$208 billion in lost productivity and \$46 billion in direct medical costs each year in the U.S. We believe Obese persons will welcome a minimally-invasive, bloodless, outpatient procedure to treat their condition as an alternative to stomach reduction surgery or lap-band surgery, which require hospitalization, have severe side effects, extended recuperation periods and can be fatal, although this cannot be assured.

**GERD** affects an estimated 20% of the population in the U.S., ranging from infants to the elderly, and according to the U.S. National Institutes of Health (“NIH”), GERD is responsible for 4.7 million hospitalizations, 1,650 deaths and 64.6 million prescriptions per year. We estimate GERD costs the U.S. healthcare system about \$40 billion per year.

**The Company’s Side Firing Fibers to treat Type II Diabetes, Obesity and GERD are expected to sell at an average worldwide price of \$3,000 each.** There is no assurance we will be able to obtain this price.

See “Marketing Strategy” under “BUSINESS” for information on the Company’s unique plan to loan its Lasers to hospitals and outpatient surgery centers that contract to buy a fixed number of Fibers per year.

### Potential Acquisition of the Company or Distribution of its Products

Large, established healthcare companies are anxious to acquire promising new therapies to expand their markets, but first want to see “proof of concept” in at least a small, randomized, controlled clinical trial.

If our direct Laser denervation of S/PS Nerves of the duodenum or the celiac artery to treat Type II Diabetes, our Laser shrinkage of the sphincter muscle of the pyloric valve of the stomach to treat Obesity, and our Laser shrinkage of the sphincter muscle of the esophageal valve to treat GERD demonstrate moderate, good or excellent clinical benefit, as determined by a panel of physicians expert in the treatment of these conditions, we believe the Company may be acquired or its products may be distributed worldwide by one of the large, established healthcare companies, although this happening cannot be assured (See “Possible Acquisition of the Company” and “Marketing Plan” under ‘BUSINESS’ for information on the possible acquisition of the Company and a possible worldwide distribution agreement for the Company’s products by an established healthcare company).

## **RISK FACTORS**

The Shares being offered under this Offering Circular are highly speculative, involve a high degree of risk and should be purchased only by parties who can afford to lose the entire amount they invest in the Company. Prospective investors should carefully consider the risks and uncertainties described below and the other information contained in this Offering Circular before making an investment in the Company. This Offering Circular contains forward-looking statements, which we are not obligated to update, and our actual results may differ materially from those described in this Offering Circular.

If any of the following risks actually occur, our business, financial condition, results of operations and ability to continue in business could be materially adversely affected, and you may lose all or part of your investment. We may also face other risks in the future which cannot presently be foreseen. **Prospective investors in this Offering should be aware of the following Risk Factors:**

1. **No Market for our Shares.**

We are privately held and, although there is no restriction against public sales of the Shares being sold in this Offering, there is no assurance a public trading market for our Shares will arise following the date of completion of this Offering and, if no trading market in our Shares arises, the purchasers of our Shares in this Offering may be unable to liquidate their investment in the Company (See "THE OFFERING").

2. **Investors in this Offering Will Suffer Significant Dilution.**

Investors purchasing Shares in this Offering will experience significant, immediate dilution of their interest in the Company. At September 5, 2014, our book value was (\$0.00) per Share. If all of the 5,000,000 Shares being offered are sold, our book value will be \$0.29 per Share, a decrease in book value of \$0.71 per Share to the purchasers of the Shares being offered and an increase in book value of \$0.29 per Share at no cost to our present shareholders (See "DILUTION").

If all of the 2,000,000 Shares reserved for issuance pursuant to our Incentive Stock Purchase plan are issued, and if all of the 2,000,000 Shares reserved for granting of stock options under our Stock Option plan are granted and exercised, we will have 19,000,000 shares outstanding, and our book value will be \$12,378,000, a decrease in book value of \$0.35 per share to the investors, and an increase in the book value of \$0.48 per share at no cost to our present shareholders.

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\* Assumes exercise at a price of \$2.00 per Share, which cannot be assured.

3. **Arbitrary Determination of Offering Price**

The offering price of our Shares was arbitrarily determined by the Company and is not based on any recognized criteria of value. There is no underwriter of this Offering, and purchasers of the Shares will not have the benefit of an underwriter's having evaluated the fairness of the offering price of the Shares.

4. **No Escrow of Funds**

There will be no escrow of the proceeds from the sales of Shares in this Offering. The proceeds received from the sales of Shares will be immediately available for use by the Company (See "THE OFFERING" & PLAN OF DISTRIBUTION").

5. **Risks of Inadequate Proceeds From the Sale of Shares**

This Offering is being made by the Company on a "best efforts" basis, and we cannot assure that any or all of the Shares being offered will be sold. Even if all of the Shares being offered are sold, the proceeds may be insufficient to meet our immediate and future needs. If we need additional financing, it may not be available to us on acceptable terms or at all, in which case our ability to continue in business will be jeopardized (See "BUSINESS" and "THE OFFERING").

6. **There Are Stock Options and Warrants That Will Dilute Your Ownership in the Company.**

6. There Are Stock Options and Warrants That Will Dilute Your Ownership in the Company.

The Board of Directors of the Company has reserved 2,000,000 Shares for issuance pursuant to a Stock Option Plan for granting of stock options to our present and future officers, directors, employees and consultants, none of which have been granted, and the Company has reserved 2,000,000 Shares for sale to Officers, directors, employees and consultants under the Company's Incentive Stock Purchase Plan, none of which have been sold. The Company has also reserved 5,000,000 Shares in the event of the exercise of the Shareholder Warrants and 1,200,000 Shares in the event of the exercise of 600,000 Selling Dealer Warrants and 600,000 Additional Selling Dealer Warrants, assuming all of the Shares being offered are sold (See 'THE OFFERING & PLAN OF DISTRIBUTION', 'CAPITALIZATION', 'DILUTION' and 'Incentive Stock Purchase Plan' and 'Stock Option Plan' under 'BUSINESS').

7. We Were Only Recently Incorporated, Have No Business and Have Limited Cash Resources

We were incorporated on August 28, 2014 and, on September 3, 2014 we had only \$30,000 of cash and cash equivalents. From the date of our incorporation to September 5, 2014, we had no revenues and our only expenses were filing fees and legal and accounting costs.

We have no business, and our only other assets are our unique product concepts, their use in the treatment of the above conditions, a unique marketing strategy and marketing plan, the Private Label Agreement with Trimedyne, the protection of Trimedyne's four (4) U.S. patents, three (3) pending U.S. patent applications, and three (3) planned patent applications, if they issue, which cannot be assured (See "Results of Operations and Liquidity" under 'MANAGEMENT'S DISCUSSION').

8. Clinical Trial and Funding Uncertainty

We plan to spend up to \$2 to \$3 million (including management, overhead and other expenses) over the next two to three years on at least four (4), 10 patient "pilot" clinical trials and up to four (4), 100 or more patient, randomized, controlled clinical trials, two of which are clinical trials of our Lasers and Fibers in the treatment of Type II Diabetes in two, different procedures, one is in the treatment of Obesity and one is in the treatment of GERD. If only 2,500,000 of the Shares being offered are sold, we will be able to conduct only the four (4) or more 10 patient "pilot" clinical trials and only one or two of the 100 or more patient, randomized, controlled clinical trials described above, based on the results of the "pilot" clinical trials. We cannot assure that our clinical trials will be successful, that we can obtain marketing clearance or approval of the FDA, the CE Mark or reimbursement by Medicare and others, or that our revenues in the future will exceed our cost of operations, the absence of which would adversely affect our ability to remain in business (See "BUSINESS").

9. We May Need Substantial Additional Financing

Even if all of the 5,000,000 Shares being offered are sold, unless our clinical trials are successful, our products are cleared or approved for sale by the FDA specifically for the treatment of the above conditions, are CE Marked for sale in the European Union and are reimbursed by Medicare specifically for the treatment of the above conditions, by other third-party payers in the U.S. and foreign governmental health programs and we generate significant sales of our products, none of which can be assured, we may need to raise additional capital, which may not be available to us at an acceptable cost or at all. If such financing is not available, we may not be able to continue in business. Sources of financing may include loans, the sale of additional equity securities or the sale of debt securities (See "BUSINESS").

10. No Assurance of Acquisition or Distribution

While large, established companies in the medical field are aggressive in acquiring small companies or distributing their products if their clinical trials have demonstrated successful results in the treatment of medical conditions, particularly those medical conditions affecting a large number of persons. There is no assurance we will be able to demonstrate clinical results sufficiently beneficial in the treatment of any of the medical conditions we are addressing to attract a purchaser of the Company or a distributor for the Company's products (See "Possible Acquisition of the Company" and "Marketing Plan" under "BUSINESS").

#### 11. Potential Acquisition Prices, Projections and Potential Market Sizes

The acquisition prices and market potentials described in this Offering Circular represent management's estimates of the possible acquisition prices, based on the Company's potential market sizes and its potential value to an acquirer or distributor, the accuracy or likelihood of which cannot be assured. To make our business attractive to an acquirer or distributor, the Company must raise capital in an amount sufficient to demonstrate in at least one clinical trial that its products are safe and effective in the treatment of at least one of the conditions it intends to treat, whose success cannot be assured. Prospective investors should not rely upon any of these projected acquisition prices, distribution expectations, marketability estimates or potential market sizes in making a decision to purchase Shares in this Offering (See "Marketing Strategy", "Possible Acquisition of the Company" and "Marketing Plan" under "BUSINESS").

#### 12. Clinical Trial, Regulatory and Reimbursement Risks.

The use of our Lasers and Side Firing Fibers specifically for the treatment of Type II Diabetes, Obesity and GERD are not presently cleared or approved for sale by the FDA and is not presently being reimbursed by Medicare or others specifically for the treatment of the above conditions. Before we can apply for (a) clearance or approval of the FDA to sell our Lasers and Fibers specifically for the treatment of Type II Diabetes, Obesity or GERD, (b) the CE Mark or (c) reimbursement by Medicare and others for the use of our Lasers and Side Firing Fibers specifically for the treatment of the above conditions, we must first complete clinical (human) trials that demonstrate their safety and therapeutic efficacy in the treatment of each of the above conditions, which can be costly and take a considerable period of time, with no assurance the outcome of such clinical trials will be successful. The FDA and foreign government authorities may require regulatory filings that may delay our clinical trials. **There is no assurance our Fibers or any modifications of these Fibers Trimedyne may make for us can be used successfully in our clinical trials or that our clinical trials using these Fibers will be successful.** There is also no assurance any Medicare reimbursement we receive will be sufficient to attract hospitals and physicians to use our products, which could affect our ability remain in business. (See "BUSINESS", "REGULATORY REQUIREMENTS" and "REIMBURSEMENT").

#### 13. Future Economic Recessions Could Impact Our Sales

The United States and many other countries are slowly recovering from a severe recession, and some countries have still not recovered from the recession. In a recession, people put-off expenditures, including expenditures for health problems, even those which involve serious conditions. Sales of our Lasers and Fibers to treat the above described conditions may be adversely affected by any future economic recessions, the extent of which cannot presently be ascertained. If we are not operating profitably, we may not be able to raise sufficient capital in the future to continue our clinical trials or marketing strategies, which could materially adversely affect our revenues, financial condition and ability to remain in business.

#### 14. We May Acquire Other Entities

While we presently have no plans to do so, we may engage in acquisitions of other companies and businesses and may use our cash reserves, authorized but unissued Shares or shares of our Preferred Stock to acquire these entities. If we use cash to make acquisitions, our cash reserves may be reduced or depleted. If we use our Shares or shares of our Preferred Stock for acquisitions, this will result in a dilution of the percentage of ownership of our Company by the purchasers of Shares in this Offering. In addition, any acquisitions we might make may involve speculative and risky undertakings. Under Nevada law, acquisitions do not require shareholder approval, except when accomplished by merger or consolidation.

#### 15. Our Stock Price May Be Volatile

The market prices for securities of medical device companies have been volatile. If any public trading market for our Shares arises, it is likely that the future price of our Shares will fluctuate. Many factors can adversely or positively affect the market price of our Shares, such as announcements of sales, earnings or losses, clinical trial results, FDA actions on applications for clearances, approvals or recalls of products, Medicare approvals or denials of coverage, the issuance or acquisition of patents or proprietary rights, lawsuits

against us, recommendations by securities analysts and market conditions in general. The market price of our Shares could also be adversely affected by future issuances of our Shares or shares of our Preferred Stock.

16. Special Risks of Our Business and The Risks of Small Businesses in the Medical Field.

Hospitals and Outpatient Surgery Centers are reluctant to buy or lease expensive pieces of equipment, as they generally have limited capital equipment budgets and credit lines. We cannot assure that we will be able to successfully sell or loan our Lasers to Hospitals and Outpatient Surgery Centers or that the revenues from the sale of Side Firing Fibers will be sufficient to offset our costs, which could adversely affect our ability to remain in business. Small companies in the medical technology field face significant risks, problems, delays, expenses and difficulties in developing, manufacturing, distributing, selling and marketing new medical technologies, especially in view of the significant competition that we will encounter in this field (See "Competition" under "BUSINESS").

17. Dependence on Key Personnel

The loss of Dr. Loeb, our Chairman, or Glenn D. Yeik, our President, will have a material adverse effect on our business. Finding replacements for capable executives in the medical device field is difficult, as there is significant competition for experienced, competent executives from both large and small companies in this industry (See "Management" under "BUSINESS").

18. Competition

The medical device business is intensely competitive, and we face competition from both large and small companies, most of whom have greater financial resources and larger management, manufacturing, R & D, marketing, sales and accounting staffs than us, which could adversely affect our ability to compete in this industry. In particular, we compete with large companies such as Johnson & Johnson, Medtronic, Abbott Laboratories, Boston Scientific and other large companies, many medium sized and many small medical device companies.

19. We May Not Be Able Adjust To Rapid Technological Changes

We are engaged in an industry in which rapid technological advances are made. There is no assurance that our present products may not face technological obsolescence, we will be able to develop, acquire distribution rights to or licenses for, or obtain regulatory approvals to market new products or keep pace with technological advances by our competitors, which could jeopardize our ability to remain in business (See "BUSINESS").

20. Risks of Developing and Marketing New Products

Developing new medical products entails considerable risk and cost. While Trimeddyne has experience in developing, manufacturing and using lasers to denervate malfunctioning S/PS Nerves and shrink tissues, we cannot assure that we can successfully conduct clinical trials of our products in the treatment of Hypertension or Stress Incontinence, that such clinical trials will be successful or we can obtain FDA and CE Mark clearances or approvals or Medicare and other third party reimbursement for the use of our products. If we cannot do so, our ability to remain in business will be jeopardized (See "BUSINESS").

21. We Are Subject To Extensive Government Regulation

Our business is subject to extensive regulation by the FDA and comparable regulatory authorities of foreign countries. Compliance with regulatory requirements and obtaining and maintaining approvals to test or market new medical devices is expensive and time consuming. Furthermore, the FDA and comparable foreign regulatory authorities may in the future change their regulations or requirements for continued marketing clearance of our products and may impose conditions on our doing so which may be costly to meet. We cannot assure that we will be able to continue to meet all regulatory requirements of the FDA and comparable foreign governmental authorities necessary to market our present products or obtain and maintain approvals to test and market any new products. Failing to meet necessary FDA and other governmental requirements will jeopardize our ability to continue in business (See "Regulatory Requirements" under "BUSINESS").

## 22. Failure to Carry Liability Insurance

We presently do not carry general liability insurance or product liability insurance. We intend to acquire such insurance from the funds raised in this Offering, but we cannot assure that we will be able to obtain or maintain this insurance in force at an acceptable cost or that the amount of this insurance will be sufficient to protect our assets in the event of claims by users of our products, patients or other parties. If court awards exceeding the amount of our insurance were made, our assets could be depleted and we may not be able to continue in business (See "Liquidity Insurance" under "BUSINESS").

## 23. We Are Dependent Upon Trimedyne Remaining in Business and Keeping its U.S. Patents in Force.

While Trimedyne had a Net Profit of \$329,000 in its fiscal year ended September 30, 2013, and had on this date \$3,414,000 of Current Assets, only \$593,000 of Accounts Payable and accrued expenses, and no long term debt outstanding, there is no assurance Trimedyne will be able to remain in business, maintain its patents in force or will be able to timely supply us with Lasers and Fibers in the future. The failure of Trimedyne to do so would have a materially adverse effect on our financial condition, results of operations and our ability to remain in business (See "BUSINESS").

## 24. We Do Not Anticipate Paying Any Dividends

We have not paid any dividends in the past and do not anticipate paying any dividends in the foreseeable future. This may depress the price of our Shares, as a non-divided paying stock may not appeal to many investors (See "BUSINESS").

## 25. Lack of Control by Investors

The Company's directors have virtually unlimited latitude in making business decisions for the Company. Since the Company's Articles of Incorporation do not provide for cumulative voting in the election of directors, the investors in this Offering, even if all of the Shares being offered are sold and their holders were to vote as a group, they will not be able to elect any of the directors of the Company or exert any influence on the Company's management, operations or policies (See "BUSINESS").

## 26. Broad Indemnification of Officers and Directors

Our By-Laws provide that we will indemnify our directors and officers to the fullest extent permitted by law, even if this indemnification is against acts for which insurance may not be available to us (See "BUSINESS").

## 27. Unaudited Financial Statements

The Financial Statements included in this Offering Circular were prepared internally by our management and have not been reviewed or audited by an independent accounting party. While these Financial Statements, in the opinion of the management of the Company, contain all adjustments of a normally recurring nature necessary for a fair statement of the Company's financial condition and its results of operations for the dates and periods indicated, we cannot assure that our Financial Statements would meet the standards of or satisfy an independent accounting firm (See "MANAGEMENT'S DISCUSSION").

## 28. New Accounting Rules or Standards

The Financial Accounting Standards Board ("FASB"), the SEC or other rulemaking authorities may issue new accounting rules or standards in the future which may adversely affect the cost of preparing our financial statements, SEC filings, if any, and our reports to our shareholders (See "MANAGEMENT'S DISCUSSION").

## FORWARD-LOOKING STATEMENTS

The Offering Circular speaks as of its date of filing with the SEC. Some of the statements under "Risk Factors" and elsewhere in this Offering Circular are forward-looking statements that involve risks and uncertainties which may exist prior to or after the date of filing of this Offering Circular with the SEC, which we are not obligated to update. These forward-looking statements include statements about our plans, objectives, expectations, intentions and assumptions, and other statements contained in this Offering Circular may not be statements of historical fact. You can identify these statements by words such as "may," "will," "should," "could," "estimates," "plans," "expects," "believes," "intends" and similar expressions. We cannot guarantee future financial results, levels of activity, performance or achievements.

Our actual results and the timing of certain events may differ significantly from those discussed in these forward-looking statements. Factors that might cause such a discrepancy include those discussed in "RISK FACTORS" and elsewhere in this Offering Circular. You are cautioned not to place undue reliance on any forward-looking statements contained in this Offering Circular.

## CAPITALIZATION

The table below indicates the capitalization of the Company as of September 5, 2014, adjusted to reflect the sale of 50% or 100% of the Shares being offered and the net proceeds therefrom:

	<u>Outstanding</u>	<u>As Adjusted, Assuming</u>	
		<u>50% Are Sold</u>	<u>100% Are Sold</u>
Stockholders' equity (deficit):			
Common Stock (\$0.001 par value); authorized			
75,000,000 Shares; 10,000,000 Shares outstanding	\$10,000	\$ 12,500	\$ 15,000
Additional paid in capital	\$20,000	\$ 2,167,500	\$ 4,365,000
Retained earnings (deficit)	\$(2,000)	\$ (2,000)	\$ (2,000)
Total stockholders' equity (deficit)	\$28,000	\$ 2,178,000	\$ 4,378,000
Total Capitalization	<u>\$38,000</u>	<u>\$ 2,178,000</u>	<u>\$ 4,378,000</u>

If only 50% of the Shares being offered are sold, we will have 12,500,000 Shares outstanding. If 100% of the Shares being offered are sold, we will have 15,000,000 Shares outstanding. In the event of (a) the sale of all of the 2,000,000 Shares reserved for sale under our Incentive Stock Purchase Plan, (b) the grant and exercise of all of the 2,000,000 Shares reserved for granting of stock options under our Stock Option Plan, (c) the exercise of all of the 300,000 or 600,000 Selling Dealer Warrants and the exercise of all of the 300,000 or 600,000 Additional Selling Dealer Warrants to be issued if 50% or 100% of the Shares being offered are sold, respectively, and (d) the exercise of 2.5 million or 5.0 million Shares underlying the Shareholder Warrants, if 50% or 100% of the Shares being offered are sold, respectively, an additional 7,100,000 or 10,200,000 Shares, respectively, would be issued, for a fully-diluted total of 19,600,000 or 25,200,000 Shares outstanding, and the investors in this Offering would then have invested a total of \$7.5 million or \$15 million in the Company and would own 25.6% or 39.7%, respectively, of the Shares of the Company then outstanding.

We are not in default or in breach of any note, loan, lease, indebtedness or financing obligation.

## DILUTION

The difference between the price of the Shares being offered and the Company's present book value per Share after the Offering constitutes substantial economic dilution to the purchasers of Shares in this Offering. Book value per Share is determined by dividing the Company's total assets by the number of outstanding Shares.

At September 5, 2014, the Company's book value was \$28,000 or \$0.00 per Share. After giving effect to the \$2,150,000 of estimated net proceeds from the sale of only 2,500,000 of the Shares being offered or the \$4,350,000 of estimated net proceeds from the sale of all of the 5,000,000 Shares being offered to the public at a price of \$1.00 per Share, the Company's pro forma book value would be \$2,178,000 or \$0.17 per Share

or \$4,378,000 or \$0.29 per Share, respectively. This represents an immediate decrease in book value of \$2,064,400 or \$0.83 per Share or \$3,540,667 or \$0.71 per Share, respectively, to the purchasers of Shares in this Offering, and an increase in the book value of \$1,714,400 or \$0.17 per Share or \$2,890,667 or \$0.29 per Share, respectively, at no cost to our existing shareholders. This presents a risk which must be carefully evaluated by prospective purchasers of the Shares being offered in this Offering.

The following Table illustrates at September 5, 2014, the dilutive effect on our book value to the purchasers of Shares in this Offering if 50% or 100% of the Shares being offered are sold, after applying the net proceeds from the sale of Shares:

**Dilution To Purchasers of Shares in This Offering, Based on the Percentage of Shares Sold:**

	Book Value Before Offering	Book Value After Offering	Decrease in Book Value to Purchasers	Increase in Book Value at No Cost to Present Holders
If 50% are Sold:	\$28,000	\$2,178,000	\$2,064,400	\$1,714,400
If 100% are Sold:	\$28,000	\$4,378,000	\$3,540,667	\$2,890,667

**USE OF PROCEEDS**

The estimated net proceeds of the Offering, if 50% or 100% of the Shares being offered are sold, after commissions of \$250,000 or \$500,000, after offering expenses of \$100,000 or \$150,000, respectively, the net proceeds of \$2,150,000 or \$4,350,000, are expected to be used over a period of at least two to three years from the Termination Date of this Offering, as follows:

<u>Purpose</u>	<u>50%</u>	<u>100%</u>
(a) Purchase ten (10) Lasers and 250 or 500 Side Firing Fibers <sup>1</sup>	\$ 600,000	\$ 750,000
(b) Cost of the Clinical Trials <sup>2</sup>	300,000	500,000
(c) Employ a CRO or our own CRO Staff for the Clinical Trials	400,000	800,000
(d) Administration, Clerical, Overhead	400,000	900,000
(e) Travel, Consulting Fees and Misc. Costs	200,000	400,000
(f) Reserve for General Corporate Purposes	<u>250,000</u>	<u>1,000,000</u>
Total Net Proceeds	<u>\$2,150,000</u>	<u>\$4,350,000</u>

<sup>1</sup> The same Laser will be used by each medical center for all of the clinical trials. However, one Laser at a medical center in Japan, after it treats its patients in the clinical trials, may be moved to another medical center in Japan to treat its patients in the clinical trials. The cost of new 30 watt Lasers and Side Firing Fibers to the Company from Trimedyne will be about \$45,000 and \$600 each, respectively. A refurbished 80 watt or 30 watt Laser may be substituted for a new 30 watt Laser.

<sup>2</sup> If only 50% of the Shares being offered are sold, four (4) or more 10 patient "pilot" clinical trials and only one (1) or two (2) of the four (4), 100 or more patient, randomized, controlled clinical trials may be conducted, depending on the results of the "pilot" clinical trials. If 100% of the Shares being offered are sold, four (4) or more "pilot" clinical trials and three (3) or four (4) of the 100 or more patient, randomized, controlled clinical trials may be conducted, depending on the results of the pilot" clinical trials.

If unexpected costs arise, there is no assurance any of the above described 100 or more patient clinical trials will be completed. The FDA or foreign government authorities may require regulatory filings that may delay the start of our clinical trials.

None of the net proceeds of this Offering will be used to pay for any services or property provided to us in the past by any of our officers, directors, employees or consultants.

If the Company's financial resources and revenues in 2014-2016 are not sufficient, after paying its costs of operations, to continue to fund the remaining cost of the clinical trials referred to above, or if unexpected costs arise, one or all of the clinical trials may have to be abandoned and the amount spent on the abandoned clinical trials will be lost (See "Our Clinical Trials" under "BUSINESS").

## **THE OFFERING & PLAN OF DISTRIBUTION**

We are presently offering up to 5,000,000 of our Shares to the public at a price of \$1.00 per Share (the "Offering") under a Form 1-A Offering Statement (comparable to a "Registration Statement") pursuant to Regulation A of the Securities and Exchange Commission (the "Commission").

There is no underwriter of this Offering of Shares of the Company. This Offering of our Shares will be conducted by the Company on a "best efforts" basis. Certain of the officers or directors of the Company will attempt to recruit broker/dealers who are member firms of FINRA to enter into Selling Dealer Agreements with the Company (the "Selling Dealers"). We can give no assurance that any Selling Dealers can be recruited to sell our Shares, that any Selling Dealers recruited will sell any of our Shares or that any or all of the Shares being offered in this Offering will be sold. The offering price of the Shares was arbitrarily determined by the Company and is not based on any established criteria of value. No pre or post-offering market capitalization of the Company can be estimated until we have operated profitably for a full year, which we cannot assure will occur.

Subscriptions for Shares are subject to acceptance by the Company, in whole or in part, in its sole discretion. To the extent a Subscription Agreement is accepted by the Company, the Subscriber will be mailed a stock certificate for the number of Shares accepted by the Company within fifteen (15) days of its acceptance, and the subscriber will receive a check refunding any part of the Subscription not accepted by the Company, but without interest thereon, within said fifteen (15) day period.

There will be no escrow of the funds received from purchasers of the Shares, and the net proceeds from sales of the Shares will be immediately available for use by the Company. We cannot assure that the proceeds of this Offering will be sufficient to carry-out our current business objectives or meet our future needs.

This Offering of Shares will terminate on the earlier to occur of (a) the sale of all of the 5,000,000 Shares being offered or (b) nine (9) months following the Date of Commencement of the sale of Shares, unless this Offering is earlier terminated by the Company (the "Termination Date").

We presently have 10 million Shares outstanding. If all of the 5 million Shares being offered are sold, we will have 15 million Shares outstanding, and the purchasers of these Shares will own 33.3% of the Shares of the Company then outstanding. If only 2,500,000 of the 5 million Shares being offered are sold, the purchasers of these Shares will own 20% of the 12,500,000 Shares of the Company then outstanding.

Within one (1) month after the Termination Date of the Offering, the Company will issue at no cost to the purchasers of Shares in this Offering, One (1) Shareholder Warrant for each Share purchased in the Offering. Each Shareholder Warrant may be exercised to purchase one (1) Share at a price of \$2.00 per Share at any time during a period of two years, commencing one year from the Termination Date of this Offering. The Shareholder Warrants contain no anti-dilution provisions, are not transferrable, except by the laws of will and descent, and must be held in registered name. The Shareholder Warrants may be redeemed by the Company at a price of \$0.001 per Warrant during their exercise period, by thirty (30) days prior written notice to their holders, if the market price of the Shares is at least \$3.00 per Share on at least five (5) consecutive trading days during the exercise period of the Shareholder Warrants.

Selling Dealers participating in this Offering will receive a commission of ten percent (10%) of the gross proceeds from the sale of Shares by each of them, if any. We will also issue at no cost to each Selling Dealer, Selling Dealer Warrants, each exercisable to purchase one (1) Share at a price of \$1.10 per Share (10% higher than the price per Share to investors in this Offering) in an amount equal to ten percent (10%) of the number of Shares sold in this Offering by each of them, if any. Each Selling Dealer Warrant may be exercised during a period of two (2) years, commencing one (1) year from the Termination Date of this Offering. If a Selling Dealer Warrant is exercised, in addition to one Share of the Company, the Selling Dealer will receive at no cost one (1) Additional Selling Dealer Warrant to purchase one (1) Share at a price of \$2.00 per Share. The Selling Dealer Warrants and Additional Selling Dealer Warrants contain no anti-dilution provisions, are exercisable on the same terms and conditions as the Shareholder Warrants, may be redeemed by the Company on the same terms and conditions as the Shareholder Warrants, are not transferable and must be held in registered name.

Officers or directors of the Company who recruit broker/dealers to act as Selling Dealers for the Company will receive, in addition to any other compensation, cash compensation of two percent (2%) of the gross proceeds from the sale of Shares of the Company by Selling Dealers recruited by each of them, if any, and each of such officers or directors of the Company shall be issued at no cost Selling Dealer Warrants and Additional Selling Dealer Warrants in an amount equal to twenty percent (20%) of the number of such Warrants issued to the Selling Dealers they each recruit, if any. The Selling Dealer Warrants and Additional Selling Dealer Warrants issued to officers or directors of the company are exercisable and redeemable, by the Company on the same terms and conditions as the Shareholder Warrants, have no anti-dilution provisions, are not transferable and must be held in registered name.

The Shareholder Warrants, the Selling Dealer Warrants and the Additional Selling Dealer Warrants are not being registered in the Registration Statement of which this Offering Circular is a part. As a result, no market for these Warrants is expected to arise.

The 5 million Shares being offered to the public in this Offering, the 10 million Shares of the company presently outstanding, the 2,000,000 Shares reserved for issuance under the Company's Incentive Stock Purchase Plan, the 2,000,000 Shares reserved for issuance pursuant to the exercise of stock options under the Company's Stock Option Plan, the 5,000,000 Shares underlying the Shareholder Warrants, the 600,000 Shares underlying the Selling Dealer Warrants and the 600,000 Shares underlying the Additional Selling Dealer Warrants, in the event all of the Shares being offered are sold, are being registered in the Offering Statement of which this Offering Circular is a part, but none of these Shares may be sold publicly until after one (1) year from the Termination Date of this Offering, subject to certain holding periods and volume limitations in the case of officers and directors of the Company and owners of 5% or more of the Company's Shares.

While the compensation of the Selling Dealers has not been submitted to, cleared with or approved by the Financial Industry Regulatory Association ("FINRA"), we believe the compensation is within FINRA's rules on compensation of Selling Dealers in "best efforts" offerings, such as this Offering.

#### Holders of Common Stock

As of September 5, 2014, we had two (2) holders of record of our Shares, the Marvin P. Loeb Research Foundation, Inc. and Trimedyne, Inc.

#### Dividends

We have never paid cash dividends on our Shares and do not anticipate paying cash dividends in the foreseeable future. Any future determination as to the payment of cash dividends will be dependent upon our financial condition, the results of operations and other factors then deemed relevant by our Board of Directors.

#### Shares Authorized For Issuance Under Equity Compensation Plans

The following table provides information as of September 5, 2014 with respect to Shares that may be issued through our equity compensation plans:

<u>Number Of Shares Available For Issuance By Exercise Of Stock Options<sup>1</sup></u>	<u>Weighted-Average Exercise Price Of Outstanding Options<sup>2</sup></u>	<u>Number Of Shares Available For Future Issuance Under Equity Compensation Plans (Excluding Shares In the first Column)<sup>3</sup></u>
2,000,000	None	2,000,000

<sup>1</sup> Under the Company's Stock Option Plan.

<sup>2</sup> No stock options have been granted under the Company's Stock Option Plan.

<sup>3</sup> Under the Company's Incentive Stock Purchase Plan.

## **MANAGEMENT'S DISCUSSION**

### **CRITICAL ACCOUNTING POLICIES**

#### **Unaudited Financial Statements**

The Financial Statements appearing in this Offering Circular were prepared internally by our management and have not been reviewed by, passed-upon or audited by any independent accounting firm or person. However, in our opinion, these Financial Statements contain all adjustments of a normally occurring nature necessary for a fair statement of the Company's financial condition as of the date specified and its results of operations for the period shown.

#### **Revenue Recognition**

We presently have no operations or revenues. When our clinical trials are completed, if successful, which cannot be assured, we will sell or rent our Lasers and Fibers. However, our future revenues are expected to consist mainly of sales of Fibers, with the Lasers being loaned to customers who contract to purchase a specified number of Fibers each year under Renewable Fiber Purchase Agreements.

In accordance with Staff Accounting Bulletin 104, "Revenue Recognition", we recognize revenue from products sold once all of the following criteria for revenue recognition have been met: (i) persuasive evidence that an arrangement exists, (ii) the products have been shipped, (iii) the prices are fixed and determinable and not subject to refund or adjustment and (iv) collection of the amounts due is reasonably assured.

Revenues from the sale of our products are recognized upon shipment and passage of title of the products to the customer, provided that all other revenue recognition criteria have been met, generally, on sales of our products, customers are required to insure the goods from our place of business. Accordingly, the risk of loss transfers to the customer once the goods have been shipped from our warehouse. We sell our products primarily through commission sales representatives in the United States. We appoint distributors to sell our products outside the United States, and we recognize revenue upon shipment, provided that all other revenue recognition criteria have been met, and ownership risk has transferred. On sales through group purchasing organizations, we may have post shipment obligations such as installation and/or in acceptance provisions, which are customarily not material.

Lasers loaned to customers that agree to purchase at least six hundred (600) Fibers per year (50 per month) will be repaired and maintained throughout the term of our Renewable Fiber Purchase Agreements at no additional cost. We reserve amounts for providing for repair and maintenance costs from our revenues from the sale of Side Firing Fibers, which are ratably recognized as costs in each following year.

In the U.S., sales of our Lasers and Fibers are paid by check in U.S. dollars. Outside the U.S., we require payment in U.S. dollars by Irrevocable Letter of Credit or Wire Transfer. As a result, we are not subject to foreign currency fluctuations.

Allowances for doubtful accounts are based on estimates of losses on customer receivable balances, based on historical losses, adjusted for current economic conditions and specific customer experience. This requires the use of judgment and assumptions, which cannot be assured. Changes in economic conditions could have a material effect on balances reserved for doubtful accounts. We presently have no revenues and have recognized no credit losses.

#### **Inventories**

Since our Lasers and Fibers are purchased under our Private Label Agreement from Trimedyne at their GAAP Cost plus 35%, Trimedyne carries all raw materials and component parts, work in process and finished good products, spare parts and accessories, and Trimedyne drop-ships these products to our customers, and

our prices are FOB, Irvine, CA, so we incur little or no warehousing or shipping costs. Inventories of products purchased from Trimedyne are recorded at the average-cost method, which approximates the first-in, first-out method.

Products provided to Hospitals or Outpatient Surgery Centers for clinical trials, sales evaluation, demonstration purposes or medical training are included in inventory, provided the products are ultimately intended to be sold or loaned under Fiber Purchase Agreements. These units are depreciated on a straight line basis over five (5) years or written down to reflect their net realizable values.

## **Goodwill**

We have adopted the provisions of Statement of Financial Accounting Standards "SFAS" No. 142, "Goodwill and other Intangible Assets." As a result of our adoption of SFAS No. 142, our goodwill is no longer amortized, but is subject to an annual impairment test, or whenever events or changes in circumstances indicate that the carrying value may not be recoverable. There was no goodwill or impairment loss recognized on goodwill through December 31, 2013.

## **Impairment of Long-Lived Assets**

SFAS No. 144, "Accounting for Impairment or Disposal of Long-Lived Assets" requires that long-lived assets, such as property and equipment and purchased intangibles subject to amortization, be revised for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of the asset is measured by comparison of its carrying amount to the undiscounted future cash flows the asset is expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amount of the asset exceeds its fair market value.

Estimates of expected cash flows represent management's best estimate, based on currently available information and reasonable and supportable assumptions. Any impairment recognized in accordance with SFAS No. 144 is permanent and may not be restored. To date, we have not recognized any impairment of long-lived assets in connection with SFAS No. 144.

## **Deferred Taxes**

We record a valuation allowance to reduce any deferred tax assets to the amount that is more likely than not to be required. The company has considered estimated future taxable income and ongoing tax planning strategies in assessing the amount needed for the valuation allowance based on these estimates. We have no deferred tax assets.

## **Stock-based Compensation**

We have not accounted for our employee stock-based compensation plans under the recognition and measurement principles of Accounting Principles Board Opinion No. 25, "Accounting for Stock issued to Employees" and related interpretations as we are presently privately-held. We plan to adopt the disclosure provisions of SFAS No. 144, "Accounting for Stock-Based Compensation," as amended by SFAS No. 148, "Accounting for Stock-Based Compensation – Transition and Disclosure," when required by law or regulation.

## **Forward-Looking Statements**

The statements contained herein that are not historical facts may consist of forward-looking statements that involve a number of known and unknown risks and uncertainties that could cause our actual results to differ materially from those discussed or anticipated in such forward-looking statements.

Potential risks and uncertainties include, among other factors, general business conditions, government regulations pertaining to medical device marketing clearances or approvals by the FDA and foreign regulatory bodies, decisions by Medicare and foreign governmental reimbursement bodies, competitive market conditions, success of our business and rental strategies, delays in receipts of orders, changes in the mix of products sold, concentration of sales in certain markets or to certain customers, development and introduction of new products, fluctuations in margins, timing of significant orders, and other risks and uncertainties.

## Results of Operations and Liquidity

We were incorporated on August 28, 2014, and from this date to September 5, 2014, we had no operations other than planning, and we had no revenues or expenses other than filing fees and legal and accounting costs.

On the date of our incorporation, we had working capital of only \$30,000.

Unless at least 50% of the Shares being offered are sold, we may not have sufficient funds to continue to operate our business for the twelve (12) months following the Termination Date of the Offering.

## BUSINESS

### General

Gastrodyne, Inc. (the "Company", "we", "our" or "us"), was incorporated under the Laws of the State of Nevada on August 28, 2014. Our office is located at 5 Holland, Suite A, Building 223, Irvine, CA and our telephone number is 1-800-951-3800, Extension 223, our toll-free telephone number is 1-800-733-5273, Ext. 233 and our website is expected to be [www.gastrodyne.com](http://www.gastrodyne.com). We are an early development stage, emerging growth company, and we presently have no business or operations.

The Company was organized by Marvin P. Loeb, Sc.D. ("Dr. Loeb") to finance and conduct at least four (4), 10 patient "pilot" clinical trials and up to four (4), 100 or more patient, randomized, controlled clinical trials of Trimedyne's proprietary Holmium laser ("Laser") and its patented and patent pending side firing fibers ("Fibers") in the treatment of Type II Diabetes (2 clinical trials), Obesity and GERD (one clinical trial each).

Trimedyne's Holmium Laser and Side Firing Fibers and improved versions thereof will be manufactured by Trimedyne for the Company, under the Company's name and trademark, under a 20 Year, Exclusive, Worldwide, Renewable, Private Label & Distribution Agreement (the "Private Label Agreement"), dated September 3, 2014.

**Trimedyne's Laser and Fibers have been cleared for sale by the FDA for use in endoscopic (gastroscopic or laparoscopic) procedures for the vaporization, coagulation, incision, and excision of tissues, respectively, called a "General Use FDA Clearance", are CE Marked for sale in the European Union and are registered in many countries that require their own registration of medical devices, including Australia, Brazil, Canada, China, Indonesia, Korea, Taiwan and other countries, but not yet in Japan. Two of the medical centers in the Company's four, 100 or more patient clinical trials are expected to be in Japan, to commence the Ministry of Health approval and regulatory process there.**

As a result of the above General Use FDA Clearance, no IDE from the FDA is expected to be required. These clinical trials are expected to be conducted at up to ten (10) or more medical centers in the U.S. under Institutional Review Board ("IRB") approvals and at up to ten (10) or more medical centers outside the U.S. under Ethics Committee approvals. The Company's Laser and Fibers will be used to treat the above described conditions in minimally-invasive, gastroscopic or laparoscopic, outpatient procedures, with only local anesthesia and sedation.

In consideration of Dr. Loeb's conceiving the laser technology to be used in the Company's clinical trials, his assigning, without royalty, to Trimedyne, two (2) U.S. Patent Applications covering (a) the denervation of nerves to treat Type II Diabetes and other conditions and (b) the shrinkage of sphincter muscles of valves to treat Obesity and GERD, his developing the clinical trial plan, his conceiving the Company's marketing strategy, his recruiting highly respected gastroenterologists to lead the Company's clinical trials and his organization of the Company, the Company privately issued for investment, without cost, seven (7) million of its Shares to the Marvin P. Loeb Research Foundation, Inc. (the "Foundation"), a non-profit Nevada corporation. Dr. Loeb is the Chairman of the Foundation, but is not an owner or a beneficiary of the Foundation.

In consideration of Trimedyn's entering into the Private Label Agreement with the Company, under which the Company received the exclusive right to market Trimedyn's Laser, Fibers and improved versions thereof for the treatment of the three (3) above conditions, subject to the Company's raising at least \$2,500,000 within one (1) year from the date of the Private Label Agreement to finance the above clinical trials, and Trimedyn's agreement to manufacture its Lasers, Fibers and improved versions thereof for the Company at Trimedyn's GAAP Cost plus 35%, instead of its usual mark-up of 60% to 200%, the Company privately sold for investment to Trimedyn three (3) million of its Shares at a price of \$0.01 each.

### **Malfunctioning Nerves Cause Arrhythmia, Asthma and Joint Pain**

The body's sympathetic and parasympathetic nerves ("S/PS Nerves") have been shown to often malfunction and send false messages to the brain, **causing or contributing to Asthma, Cardiac Arrhythmia and Spinal Joint Pain, and may cause or contribute to Type II Diabetes.** Dr. Loeb believes denervating (coagulating) and interrupting a sufficient amount of these malfunctioning S/PS nerves, as they pass from the intestines through the duodenum and the celiac artery on their way to the brain, can stop the transmission of these false messages to the brain and treat or at least partially relieve Type II Diabetes.

**In persons suffering from Type II Diabetes, their body makes insulin, but it cannot be properly absorbed in their intestines. Dr. Loeb believes malfunctioning "S/PS Nerves" of the intestines may cause Type II Diabetes by sending false messages to the brain that the body's insulin is a foreign substance, causing the brain to activate the immune system to destroy or alter it and instructing glands to produce enzymes to decompose it, so it will not activate receptors in the intestines, permitting its absorption. Type II Diabetes is also known as "insulin absorption resistance".**

In the Company's two (2), 10 patient "pilot" clinical trials and its two (2), 100 or more patient clinical trials to treat Type II Diabetes, we will denervate (coagulate) these malfunctioning S/PS Nerves (a) in the wall of the duodenum in a gastroscopic procedure from inside the duodenum or (b) in the outer layer and on the exterior of the celiac artery, where it exits the duodenum, in an laparoscopic procedure from outside the celiac artery, to determine which procedure produces the best clinical results.

**Trimedyn's Holmium Lasers and Fibers have been used for more than 18 years since 1996 to denervate malfunctioning S/PS Nerves of spinal joints to treat severe back pain, with high published success rates and long term persistence of the denervation effect.**

Trimedyn has been assigned by Dr. Loeb, without royalty, a U.S. Patent Application covering its Laser and Fibers and other sources of focused thermal energy to denervate malfunctioning nerves to treat Type II Diabetes and a number of other conditions. The success of our two nerve denervation procedures to treat Type II Diabetes and the issuance of Trimedyn's pending U.S. Patent Application cannot be assured.

### **Loose Valves Cause GERD, Heart Valve Leakage and Incontinence**

Loose sphincters of valves occur in humans and have been shown to cause Gastro Esophageal Reflux Disease or "GERD", by allowing stomach acids to leak into the esophagus through a loose esophageal valve and erode the sensitive inner lining of the esophagus, leakage of blood occurs from loose heart valves, urinary incontinence occurs by leakage of urine through a loose urethral or bladder neck valve, fecal incontinence occurs by leakage of fecal matter used through a loose anal valve.

**Dr. Loeb believes, if a person is born with a loose pyloric valve at the bottom of the stomach, partially digested food continuously flows into the duodenum and intestines, the stomach is never full, the patient does not feel "full" and continues to eat, causing or contributing to Obesity.** He also believes the occurrence of a loose pyloric valve may be a genetic pre-disposition, as obesity is often seen in the children of an obese parent.

Holmium laser energy has the unique ability to photomechanically cross-link collagen, a constituent of all soft tissues of the body, causing it to shrink by 10% to 25% the instant Holmium laser energy touches the tissue.

This Laser shrinkage effect may shrink the sphincter muscle and tighten a loose pyloric valve to treat or relieve Obesity and shrink the sphincter muscle and tighten a loose esophageal valve to treat or relieve GERD, although our success in doing so cannot be assured.

**Trimedyne's Holmium Laser and Side Firing Fibers have been used for 20 years, since 1994, to shrink tissues in Orthopedics, for example, to shrink the capsule of the shoulder in people who frequently dislocate their shoulder, and to shrink herniated "bulging" discs in the spine**

**To view an 84 second DVD on our Laser shrinking the capsule of the shoulder, Right click on <https://vimeo.com/104754523>, select "Open Hyperlink", then click on the Left Arrow to view the DVD.**

Trimedyne has been assigned by Dr. Loeb, without royalty, a U.S. Patent Application covering its Laser and Fibers and other sources of focused thermal energy to shrink loose valves to treat Obesity, GERD and a number of other conditions. The success of our two valve shrinkage procedures to treat Obesity and GERD and the issuance of Trimedyne's pending U.S. Patent Application on the use of its Laser and Fibers to shrink valves cannot be assured.

### **Clinical Trial Management**

Professor Peter J. Kahrilas, M.D., former Chairman of the Department of Gastroenterology, and Professor John E. Pandolfino, M.D., the present Chairman of the Department of Gastroenterology of the Feinberg School of Medicine of Northwestern University, have agreed to be the Co-Principal Investigators of the Company's four (4) or more 10 patient "pilot" clinical trials and its four (4) 100 or more patient clinical trials.

Professors Kahrilas and Pandolfino will select and train Investigators in the U.S., Canada and Mexico, and they will select and train a Regional Chief Investigator for Central and South America, a Regional Chief Investigator for Europe and the Middle East and a Regional Chief Investigator for Eastern Europe, SE Asia and Asia, who will each select and train Investigators in their respective areas.

Professors Kahrilas and Pandolfino will prepare the Protocols for the "pilot" clinical trials and the Protocols for the 100 or more patient, randomized, controlled clinical trials, oversee these clinical trials and, when the trials are completed, they will prepare papers on the results of the clinical trials for submission to a respected, peer reviewed, medical journal appropriate for each of the medical conditions. Professors Kahrilas and Pandolfino are among the leading experts in the world in gastroscopic procedures to treat GERD and other gastroenterological conditions.

The Company plans, if and when the Lasers and Fibers are cleared for sale or approved by the FDA specifically for the treatment of the above conditions and are reimbursed by Medicare specifically for the above conditions, to use the Enterology Center of Northwestern University's medical school as its primary training center for gastroenterologists.

Professor Kahrilas is the President of the International Society for Diseases of the Esophagus, is a member of the Editorial Board of 11 medical journals, a reviewer for 34 medical journals, received 32 honors or awards for his work, is the author or co-author of 72 published papers or medical journal articles, has written 58 published editorials, letters or book reviews, has been an invited lecturer at 18 medical schools or hospitals throughout the world and has been the principal or co-principal investigator of 5 medical research grants over the past six years.

Professor Pandolfino is Editor in Chief of Diseases of the Esophagus, a member of the Editorial Board of Gastroenterology, the American Journal of Gastroenterology, and Clinical Gastroenterology & Hepatology, is the author or co-author of 84 published papers, 44 reviews and 5 editorials, has written 15 book chapters and has been an invited speaker at 10 medical schools or hospitals throughout the world.

## **The Conduct of our Clinical Trials**

All of the Company's 100 or more patient, randomized, controlled clinical trials are expected to be conducted in the U.S. under Institutional Review Board ("IRB") approvals and outside the U.S. under Ethics Committee approvals. All prospective patients in the Company's "pilot" clinical trials and 100 or more patient clinical trials must sign a Patient Informed Consent Form prior to enrollment or treatment in any of our clinical trials.

All of the patients enrolled all of in the ten (10) patient "pilot" clinical trials and the four (4), 100 or more patient, randomized, controlled clinical trials (Laser Treated and Controls) are expected to receive optimal medical (drug) therapy during the "pilot" clinical trials and throughout the 100 or more patient, randomized, controlled clinical trials.

The follow-up periods of the four (4), 100 or more patient, randomized, controlled clinical trials are expected to end at one (1), six (6) and twelve (12) months following the date the patient is discharged from the medical center. The follow-up period of the "pilot" clinical trials are expected to end at one (1) month after such discharge. The FDA and foreign government authorities may require regulatory filings that may delay our clinical trials.

An Independent Data Committee will analyze the data from the Company's 100 or more patient clinical trials. The patients, the interviewers of the patients and the reviewers of the patient data will be blinded as to which procedure the patient received.

## **Pre-Clinical Trial Testing**

Prior to conducting any of the four (4), multi-center, 100 or more patient, randomized, controlled clinical trials, the Laser and Fibers will be tested in one or more 10 patient "pilot" clinical trials in the treatment of each of Type II Diabetes, Obesity and GERD outside the U.S., where such testing costs much less than in the U.S., under the direction of Professors Kahrilas and Pandolfino. If the first "pilot" clinical trial of a condition indicates the level of laser energy or the pulse repetition rate should be changed, another 10 patient "pilot" clinical trial will be conducted to confirm that the change properly treats the condition.

Another benefit of these 10 patient, "pilot clinical trials is their clinical results can be evaluated to determine if they merit the cost of their larger, more expensive 100 or more patient, randomized, controlled clinical trials. If, based on the results of its "pilot" clinical trials, if one or more of the larger, 100 or more patient clinical trials is deferred until the level of Laser energy is changed or the Fiber is improved, it would enable the Company to increase the number of patients in the other clinical trials, increasing the likelihood of their obtaining specific FDA clearance and specific Medicare reimbursement, although such cannot be assured.

## **Our Randomized Controlled Clinical Trials**

In each of the four (4), 100 or more patient, randomized controlled clinical trials, at least 50 patients suffering from Type II Diabetes (2 clinical trials), Obesity or GERD (one clinical trial each), are expected to be randomly assigned to a Laser Group, one for each of the four (4) clinical trials, and at least 50 patients suffering from one of the three above conditions are expected to be randomly assigned to a Control Group, one for each of the four (4) clinical trials.

The patients in the Laser Groups of the two (2), 100 or more patient clinical trials in the treatment of Type II Diabetes will receive either a gastroscopic laser procedure to denervate S/PS Nerves in the wall of the duodenum from inside the duodenum, or a laparoscopic laser procedure to denervate S/PS Nerves in the outer layer and on the exterior of the celiac artery from outside the celiac artery. The patients in the Laser Groups of the two (2), 100 or more patient clinical trials in the treatment of Obesity or GERD will receive a laser gastroscopic procedure to shrink and tighten the sphincter of their pyloric valve or esophageal valve, respectively.

The patients in each of the four (4) Control Groups are expected to receive a "sham" procedure in which the gastroscope or laparoscope will be positioned and the Fiber will be advanced out of the scope, rotated and advanced, as described below in "Our Gastroscopic Procedures", but no laser energy will be emitted.

In these clinical trials, it is important to avoid damage to the inner lining of the duodenum, pyloric valve or esophagus. The Company's Holmium Laser is pulsed and emits 350 microsecond (350 millionths of a second) pulses of laser energy. A second consists of one million microseconds. For example, at a pulse repetition rate of ten (10) pulses per second, a second consists of 10 segments of 100,000 microseconds each. **After each 350 microsecond pulse of laser energy, there are 99,650 microseconds for the tissue to cool before the next pulse of laser energy, a ratio of cooling time to lasing time of 285:1.**

Also, Holmium Laser energy penetrates tissue to a depth of only 0.4 mm (1/60<sup>th</sup> of an inch), with thermal energy diffusion expanding the treatment area to about 1 mm (1/25<sup>th</sup> of an inch), avoiding or minimizing damage to the duodenum, pyloric valve or esophageal valve, although avoiding such damage cannot be assured.

**There is no assurance our Fibers or any modifications of these Fibers Trimedyne may make can be used successfully in our clinical trials or that our clinical trials using these Fibers will be successful.**

If the Company does not have the funds to complete any or all of the four (4), 100 or more patient clinical trials, the funds used in such clinical trials will be lost.

### Our Gastroscopic Procedures

At the start of our Gastroscopic Procedure to denervate malfunctioning SP/S Nerves of the duodenum to treat **Type II Diabetes**, a flexible, steerable gastroscope ("Scope") is advanced to near the proximal end of the duodenum. A Nerve Activity Sensor, which is expected to be manufactured for the Company under its name and trademark, which has been cleared for sale by the FDA and is CE Marked, is inserted through the Scope, which will be angled to bring the Nerve Activity Sensor into light contact with the inner surface of the duodenum to measure its level of nerve activity.

The Nerve Activity Sensor is then withdrawn, the Fiber is inserted through the Scope and laser energy is emitted, as described below, to denervate malfunctioning S/PS Nerves of the duodenum to treat **Type II Diabetes**. The Fiber is withdrawn and the Nerve Activity Sensor is again inserted to measure the level of nerve activity. This process is repeated until the level of nerve activity falls to the level of nerve activity in persons not suffering from Type II Diabetes.

At the start of our Gastroscopic Procedures to shrink the pyloric valve of the stomach to treat **Obesity** or to shrink the sphincter of the esophagus to treat **GERD**, the Scope is positioned at the proximal end of the sphincter of the pyloric valve or the proximal end of the esophageal sphincter. An Opening Pressure Sensor, which is expected to be manufactured for the Company under its name and trademark, which has been cleared for sale by the FDA and is CE Marked, is inserted through the instrument channel of the Scope and the balloon at its distal end is inflated with sterile water or saline. Sensors in the balloon measure the opening pressure or "resistance to distention" of the pyloric valve of the stomach or the sphincter of the esophagus, which is displayed on a Monitor outside the body.

The Opening Pressure Sensor is then withdrawn, and the Fiber is inserted and laser energy is emitted as described below. The Fiber is withdrawn, the Opening Pressure Sensor is inserted and the opening pressure is again measured. This process is repeated until the opening pressure of the pyloric valve or the esophageal valve reaches the opening pressure (resistance to distention) of persons not suffering from Obesity or GERD, respectively.

In each of the above nerve denervation or valve shrinkage procedures, for fifteen (15) seconds prior to and throughout each emission of laser energy, a cold spray of sterile water or saline is infused through the Scope to cool the sensitive epithelial lining of (a) the duodenum, (b) the pyloric valve of the stomach and (c) the esophagus overlying its sphincter. The Scope is angled to position the laser energy emitting surface of the Fiber close to but not in contact with the sensitive epithelial lining of the duodenum, the pyloric valve or the esophagus overlying its sphincter.

In all three (3) of the gastroscopic procedures, laser energy is emitted at a level of only 300 millijoules per pulse and at a short pulse duration of only 350 microseconds. The pulse repetition rate, initially ten (10) pulses per second (3 watts), is increased in steps of 5 pulses per second until (a) the tissue of the duodenum is

seen to blanch (turn white), indicating that the nerves have been coagulated, (b) the pyloric valve of the stomach is seen to shrink or (c) the esophagus overlying its sphincter is seen to shrink.

During the emission of laser energy, the Fiber, which is extended from the Scope, is repetitively rotated, back and forth, through three, 120° arcs around the inner surface of the duodenum, the pyloric valve of the stomach or the esophagus underlying the esophageal sphincter, each for sixteen (16) seconds, for example, from 12 o'clock to 4 o'clock, then from 4 o'clock to 8 o'clock and last from 8 o'clock to 12 o'clock, like the beacon of a lighthouse, at the rate of two arcs per second, without pausing at any point, for a laser energy emission time of 48 seconds. The surgeon can mentally count "one thousand" to time each arc. **The "residence time" of the beam of laser energy is a tiny fraction of a second at any point in each arc.**

Also, Holmium Laser energy penetrates tissue to a depth of only 0.4 mm (1/60<sup>th</sup> of an inch). The surrounding liquid (sterile water or saline) carries-away heat from the surface of the tissue. However, laser energy accumulates beneath the surface of the tissue, which does not have the benefit of the surrounding liquid or cold spray of sterile water or saline, in an amount believed sufficient to shrink the sphincter of the pyloric valve or the esophageal valve.

After each of the three (3) above described 120° rotation processes, the Scope and Side Firing Fiber are advanced 0.5 cm (0.2 inches). When all three (3) of the above 120° rotation and advancement processes are completed, the Scope and the Side Firing Fiber are advanced 1 cm (0.4 inches) beyond the last 120° rotation point, and another three, 120° advancement and rotation processes, as described above, are performed, repeating the denervation or shrinkage procedure, for a total laser energy emission time of 96 seconds for each procedure, unless the surgeon wishes to repeat any of the laser energy emissions.

The combination of (a) the Company's Holmium Laser emitting laser energy at a very low level in very short 350 microsecond pulses, allowing the sensitive epithelial lining of the tissue to cool between the pulses of laser energy, (b) Holmium Laser energy penetrating tissue to a depth of only 0.4 mm (1/60<sup>th</sup> of an inch), (c) the Fiber being repetitively rotated, back and forth, like the beacon of a lighthouse, through three 120° arcs, each for 16 seconds, without pausing at any point, as described above, and (d) the infusion of a spray of cold, sterile water or saline through the Scope to cool the sensitive epithelial lining of the duodenum, pyloric valve of the stomach or the esophagus underlying its sphincter, **the laser energy is expected to have too low an energy density and too short a residence time to damage the wall of the duodenum, the pyloric valve or the esophagus**, although such cannot be assured.

However, within the tissue underlying the epithelial inner lining of the duodenum, the pyloric valve of the stomach or the esophagus, which does not have the benefit of the cold spray of sterile water or saline, laser energy is expected to accumulate in an amount sufficient to uniformly denervate malfunctioning S/PS Nerves of the duodenum and shrink the sphincter of the pyloric valve of the stomach and the sphincter of the esophageal valve. However, obtaining this effect cannot be assured.

### **Our Laparoscopic Procedure**

The Company has a developed Laparoscopic Procedure for the treatment of Type II Diabetes by denervating S/PS Nerves in the outer layer and on the exterior of the celiac artery, which will also be tested in one or more 10 patient "pilot" clinical trials and one (1) 100 or more patient, randomized, controlled clinical trial to compare the efficacy of its Laparoscopic Procedure to treat Type II Diabetes with that of its Gastroscopic Procedure to treat Type II Diabetes, to determine which Procedure is most effective.

A semi-rigid laparoscope ("Scope"), whose distal 10 to 15 cm is flexible and can be articulated (bent) by wires up to 90° or more, will be inserted through a small incision or trocar puncture in the belly-button into the abdomen, which is inflated with CO<sub>2</sub> gas to distend the abdomen, provide working room, a clear field of view and enable the surgeon to maneuver the Scope around other organs and vessels. This laparoscopic procedure is often referred to as "Belly-Button Surgery". The insufflator to infuse CO<sub>2</sub> gas and other instruments are inserted through other small trocar punctures through the abdominal wall. Trocars produce cuts, rather than holes in the abdominal wall and typically heal quickly.

The distal end of the Scope is positioned parallel to the Celiac Artery, starting about 5 cm (2 inches) from the point where the Celiac Artery branches into the duodenum. The Nerve Activity Sensor is inserted into and extended out of the Scope until it lightly contacts the exterior of the celiac artery. The Nerve Activity Sensor is used to determine the level of nerve activity of the celiac artery, as described above. The Nerve Activity Sensor is then removed and the Fiber is inserted through the Scope.

A spray of cold, sterile water or saline is infused through the Scope to cool the exterior of the celiac artery for 15 seconds prior to and throughout each emission of laser energy. Laser energy is emitted at the laser parameters described above, and the Fiber is successively rotated, back and forth, through three (3) 120° arcs, first from 12 to 4 o'clock, then from 4 to 8 o'clock and last from 8 to 12 o'clock around the celiac artery, like the beacon of a lighthouse, at the rate of two (2) arcs per second, without pausing at any point, for a period of 16 seconds for each arc. The Scope and Fiber are advanced 0.5 cm (0.2 inch) after each of the three (3) 120° rotation processes, as described above.

The Scope and Fiber are then advanced about 1 cm (0.4 inches) and the three 120° rotation, energy emissions and advancement processes are repeated. The Fiber is withdrawn and the Nerve Activity Sensor is inserted through the Scope and is again used to measure the nerve activity level of the celiac artery.

If the level of nerve activity of the Celiac Artery has not fallen to about the level of nerve activity level of persons not suffering from Type II Diabetes, additional sets of three 120° rotations and laser energy emissions are repeated until the Nerve Activity Sensor indicates the level of nerve activity has reached about the level of nerve activity in persons not suffering from Type II Diabetes.

Since the pulse duration of the Company's Laser is only 350 microseconds, allowing the tissue to cool between pulses, the residence time of the beam of laser energy is only a tiny fraction of a second at any point in each of the Fiber's 120° arc rotations, Holmium Laser energy's penetrating tissue to a depth of only 0.4 mm (1/60<sup>th</sup> of an inch) and the cooling spray of sterile water or saline, damage to the exterior of the celiac artery is expected to be avoided or minimized, although such cannot be assured.

### **Potential Market Sizes**

**Diabetes** affects an estimated 26 million people in the U.S, about 90% or 23.4 million of whom have Type II Diabetes. Another 79 million Americans have pre-diabetes which, over time, often progresses to Type II Diabetes. According to the U.S. Centers for Disease Control ("CDC"), the treatment of **Diabetes** and its adverse effects, which include heart attacks, congestive heart failure, peripheral artery disease, amputations, hypertension, kidney failure and blindness, costs \$174 billion each year in the U.S. **About ten percent of all U.S. healthcare dollars is spent on treating Diabetes and its adverse effects.**

**Obesity** affects millions of people in the U.S. According to the American Heart Association ("AHA"), 154.7 million people in the U.S. are overweight or obese, of which 78.4 million are **obese**. The cost of being overweight or obese is estimated at \$208 billion in lost productivity and \$46 billion in direct medical costs. We believe Obese persons will welcome a minimally-invasive, bloodless, outpatient procedure to treat their condition, as an alternative to stomach reduction surgery or lap-band surgery, both of which entail infections and other severe side effects, extended recuperation periods and the risk of death, although acceptance of the Company's Laser procedure to treat Obesity cannot be assured.

**GERD** affects an estimated 20% of the population in the U.S., ranging from infants to the elderly, according to the U.S. National Institutes of Health ("NIH"), and GERD is responsible for 4.7 million hospitalizations, 1,650 deaths and 64.6 million prescriptions per year. We estimate GERD costs the U.S. healthcare system about \$40 billion per year.

**Our Side Firing Fibers to treat Type II Diabetes, Obesity and GERD are expected to sell at an average worldwide price of \$3,000 each.** There is no assurance we will be able to obtain this price.

## Possible Acquisition of the Company

Large, established healthcare companies are anxious to acquire companies with promising new therapies to expand their markets, but first want to see “proof of concept” in a small, randomized, controlled clinical trial.

When the six (6) or twelve (12) month results of the Company’s 100 or more patient clinical trials in the treatment of Type II Diabetes, Obesity and GERD are available, we believe the Company may be acquired by one of the large, established healthcare companies, although this cannot be assured.

For example, if the Company’s treatment for any of Type II Diabetes, Obesity or GERD is found by a physician panel, consisting of experts in the treatment of Type II Diabetes, Obesity and GERD to produce only “moderate” clinical benefit, the Company is expected to be acquired at an estimated price of \$400 million, and the acquirer will distribute the \$400 million to the holders of Gastrodyne’s Shares then outstanding.

Assuming all of the 5,000,000 Shares being offered are sold, all of the 2,000,000 Incentive Stock Purchase Shares have been sold, all of the 2,000,000 Stock Options, 5,000,000 Shareholder, Warrants and 600,000 Underwriter Warrants and 600,000 Additional Underwriter Warrants have been exercised, we will have a total of 25,200,000 Shares outstanding, and the acquisition price would be **about \$16.00 per share, about 16 times the present Offering price of \$1.00 per Share.** The Company may also receive an “earn out” based on future sales, which will be distributed by the acquirer annually to the holders of our Shares then outstanding. There is no assurance any of the Company’s clinical trials will be successful or that we will be acquired by a large, established healthcare company or, if acquired, that the price will be as high as illustrated above.

If a price of \$400 million for the Company seems too high, in 2011, Medtronic paid **\$800 million** plus an “earn-out” based on future sales, for a start-up, Ardian, Inc. Ardian conducted only a **106 patient**, randomized, controlled clinical trial outside the U.S. in the treatment of Uncontrolled Hypertension, with its published six (6) month results demonstrating only a 33 mm reduction in systolic pressure, a modest clinical benefit in the treatment of Uncontrolled Hypertension. A 33 mm reduction in systolic pressure cannot normalize a person whose systolic pressure is 200 to 300 mm (140 mm or less is normal). Uncontrolled Hypertension is a very large market and its treatment is estimated to cost \$65 billion per year in the U.S. We believe Type II Diabetes is a much larger market than the Uncontrolled Hypertension market, and Obesity and GERD are a larger market than the Uncontrolled Hypertension market.

If the Company’s 100 or more patient clinical trial in the treatment of either (a) Type II Diabetes or (b) Obesity and GERD produces “good” or “excellent” clinical benefits, as determined by a panel of physicians expert in the treatment of these conditions, we believe an acquisition price of **\$800 million or more** is possible, plus an “earn-out” based on future sales, although obtaining this price cannot be assured.

The Company offers a “first mover” advantage as, to our knowledge, we are the first company to use Lasers and Fibers to denervate nerves of the duodenum or celiac artery to treat Type II Diabetes, shrink the pyloric valve to treat Obesity or shrink the esophageal valve to treat GERD in minimally-invasive gastroscopic or laparoscopic, outpatient, Laser procedures, as described above, and Trimedyn has two (2) pending U.S. Patent Applications covering its Lasers and Fibers and other sources of thermal energy for (a) the denervation of nerves of the duodenum or the celiac artery to treat Type II Diabetes, or (b) shrinking loose valves to treat Obesity or GERD, and other conditions. The first company to enter a new medical field often dominates the field.

## Marketing Plan

If no acceptable acquisition offer is received from a large, established healthcare company and, if the results of any of the Company’s four (4), 100 or more patient, randomized, controlled clinical trials are as successful as we believe, which cannot be assured, when the six or twelve month results of these clinical trials are available, we may be able to enter into an Exclusive Distribution Agreement with a large, established healthcare company to market our Lasers and Fibers throughout the world for the treatment of such conditions, or we may be able to conduct a second round of public or private financing and use the proceeds to establish a sales organization to market our Lasers and Fibers throughout the world for the treatment of such conditions. There is no assurance any of our clinical trials will be successful, we can enter into such a Distribution Agreement with a large, established healthcare company, we will be able to raise sufficient funds to establish a sales organization or we will be able to successfully market our Lasers and Fibers throughout the world.

When the 6 and 12 month results of each of the four (4), 100 or more patient clinical trials are published, the Company will hold Press Conferences in the U.S. and at each hospital outside the U.S. participating in its clinical trials, at which the Investigators will discuss the results of the clinical trial, show videos of the procedures and give DVDs on the procedures to the media. Wide media coverage is expected to increase the demand for our Lasers and Side Firing Fibers.

Following these press conferences, since the Company's Laser and Fibers are cleared for sale by the FDA for use in endoscopic (gastroscopic or laparoscopic) procedures, are CE Marked for sale in the European Union and are registered for sale in many countries, we can commence marketing our Lasers and Fibers in the U.S. under our existing FDA clearances for use in endoscopic (gastroscopic or laparoscopic) procedures, in the European Union under our existing CE Marks, under our existing individual country registrations and elsewhere throughout the world, until specific FDA marketing clearance and specific reimbursement by Medicare and foreign government health programs for the treatment of the above conditions is received, which will increase the appeal of our products to hospitals, outpatient surgery centers and physicians, although our accomplishing this cannot be assured.

### **Marketing Strategy**

Hospitals and outpatient surgery centers are reluctant to purchase expensive capital equipment, such as the Company's \$150,000 30 watt "pulsed" Holmium Laser, and buying decisions on capital equipment can be delayed in Budget and Purchasing Committees for months. However, the price of our disposable Side Firing Fibers and the amortization cost of the \$150,000 Holmium Laser will be included in the reimbursement rate. This may result in a reimbursement rate sufficiently high to make the expected \$3,000 price of the Fiber affordable to hospitals and surgery centers, although this cannot be assured. For comparison, the price of Medtronic's RF catheter to treat Uncontrolled Hypertension in the European Union and other developed countries outside the U.S. was reported to be \$5,000 each.

To penetrate the market rapidly, under Dr. Loeb's marketing strategy, the Company plans to loan its Lasers to hospitals and outpatient surgery centers that contract to purchase at least 600 Fibers per year (50 per month), at an expected, average worldwide price of \$3,000 each, under One-Year or Three Year, Renewable Fiber Supply Agreements, which could generate sales of \$1.8 million or more per hospital per year, although this cannot be assured. Our One-Year, Renewable, Fiber Purchase Agreements are limited to Military Hospitals, VA Hospitals and County Hospitals, which are usually not allowed to contract for disposable supplies for longer than one (1) year.

The first month's purchase of 50 Fibers at an expected, average worldwide price of \$3,000 each, creates \$150,000 of revenue and, at a profit margin of 80%, more than offsets the \$45,000 cost of the Laser from Trimedyne, installation, training and freight costs.

Four to five years after commencing the sales of its products, if we have loaned our Lasers to only 600 or 1% of the more than 60,000 hospitals and surgery centers throughout the world under the above terms, the Company could generate revenues of at least \$1.08 billion per year. There is no assurance we will be able to afford a worldwide sales organization to obtain such number of Fiber Purchase Contracts.

To be sure its loaned Lasers are available to treat patients and consume disposable Fibers, the Company will pay Trimedyne, at its GAAP Cost plus 35%, to repair and maintain the Lasers loaned to its customers free of charge throughout the terms of the Company's Fiber Purchase Agreements, after Trimedyne's one-year warranty expires (See "Field Service").

There is no assurance the average \$3,000 Contract price per Fiber can be obtained, that hospitals and outpatient surgery centers will commit to purchasing 600 Fibers per year for one or three years at such price, that the revenues described above can be attained or that Trimedyne will be financially able to establish a worldwide field service organization to repair and maintain the Lasers we loan to customers.

### **The Private Label Agreement**

Trimedyne has entered into a Twenty Year, Renewable, Exclusive, Worldwide Private Label and Distribution Agreement (the "Private Label Agreement") with the Company dated September 3, 2014, under

which Trimedyne will manufacture its Lasers, Fibers and improved versions of each for the Company at Trimedyne's "GAAP" Cost plus 35%, and Trimedyne will grant the Company the exclusive, worldwide right to distribute its Lasers and Fibers for the Treatment of Type II Diabetes, Obesity and GERD, subject to the Company's raising at least \$2.5 million within one (1) year from the Date of the Private Label Agreement.

Trimedyne will also repair and maintain Lasers sold by the Company during their one-year warranty period at no charge and, after the Warranty period expires, Trimedyne will charge their owners Trimedyne's GAAP Cost plus 35% for parts and labor services. Trimedyne will also repair and maintain the Lasers loaned to the Company's customers throughout the term of their Fiber Purchase Agreements at no charge and, after its one year warranty expires, will charge the Company for parts and labor services to the Company's customers at its GAAP Cost plus 35%.

The Company's cost for Side Firing Fibers from Trimedyne will be about \$600 each. At an expected, average, worldwide selling price of \$3,000 each, this will provide a gross margin of 80% for the Company. The Company's cost for 30 watt, pulsed Holmium Lasers from Trimedyne will be about \$45,000 each and, at an expected, average worldwide selling price of \$150,000, the Company will have a gross margin of 70%. Our ability to obtain such prices from hospitals and outpatient surgery centers cannot be assured.

**The above "GAAP cost plus" prices from Trimedyne to the Company are expected to significantly decline as the volume of Lasers and Fibers increases, raising the Company's gross margins, although such cannot be assured.**

The Private Label Agreement with Trimedyne will enable the Company to use Trimedyne's FDA clearances, CE Marks, ISO Certification and registrations in countries outside the U.S. and the European Union that require separate registration of medical devices, including Australia, Brazil, Canada, China, Indonesia, Korea, Taiwan and other countries, which can take a year or longer to obtain.

The Private Label Agreement will also enable the Company to concentrate on recruiting a full-time, experienced and highly qualified management, marketing and sales team and concentrate on its clinical trials, **which will establish the Company's value in the marketplace.**

If the Company did not have the benefit of this Private Label Agreement, the Company would have to spend an estimated 5-6 years of time and an estimated \$20 million to develop, test and obtain FDA clearances for its Holmium Lasers and Side Firing Fibers and establish, equip and staff an FDA approved, ISO Certified manufacturing facility to produce them, **but it would not have the protection of Trimedyne's Patents and Patent Applications.**

Trimedyne has spent more than \$44 million in R&D over the past years to develop its lasers and fiber-optic devices (an audited figure), of which an estimated \$15 million was spent in developing and testing its Holmium Laser, Side Firing Fibers and improved versions of these devices.

The Lasers and Fibers to be supplied to the Company by Trimedyne are protected by four (4) U.S. Patents, three (3) pending U.S. Patent Applications and three (3) U.S. Patent Applications being prepared for filing in the U.S. and major countries outside the U.S. These Patents and the Patent Applications, if issued, will create a multi-year barrier to competition, although this cannot be assured.

The Company will contract directly with manufacturers of gastroscopes, laparoscopes, nerve activity sensors and monitors, opening pressure sensors and monitors and other non-laser instruments used in its therapies for Type II Diabetes, Obesity and GERD.

### **Field Service**

Trimedyne plans to broaden its U.S. and foreign field service organization and establish field service facilities to repair and maintain Lasers we sell or loan to our customers. We will pay Trimedyne, at its GAAP Cost plus 35%, to repair and maintain the Lasers we rent to customers, after Trimedyne's one year Warranty expires.

The Company reserves from its sales of Fibers under Fiber Purchase Agreements, the anticipated cost of repairing and maintaining the Lasers it loans to its customers, after Trimedyne's one-year Warranty expires.

The Company may advance part of these reserves to Trimedyne to enable it to expand its field service organization and field service facilities to repair and maintain the Lasers we loan to customers.

There is no assurance we and/or Trimedyne will be able to afford the cost of establishing and operating a worldwide field service organization and field service facilities to repair and maintain the Lasers we sell or loan to our customers.

## **Management**

The Company has a management team with the intelligence, experience, vision and drive to make us an extraordinarily successful and profitable enterprise.

Marvin P. Loeb, Sc.D., is the founder and Chairman of Trimedyne and the Chairman of the Company.

Trimedyne's President, V.P. Sales, Director of Operations, Director of Regulatory and QA/QC and others will serve in their present capacities for the Company on a part-time basis. The Company will reimburse Trimedyne on a pro-rata basis for the time they devote to the Company, including fringe benefits, and the Company may pay them, through Trimedyne, a discretionary bonus based on their performance, until experienced, talented executives are hired on a full-time basis to replace any of them. In addition to the Company's contacts in the healthcare field, the Company works with The Coelyn Group, a nationwide employment recruiting firm that specializes in the healthcare field.

## **Board of Directors**

Donald Baker<sup>1</sup>

Marvin P. Loeb, Sc.D.<sup>2</sup>

Glenn D. Yeik<sup>3</sup>

Three additional directors will be chosen from the investors in the Offering, and the new President of the Company, if and when hired, will also be elected a Director of The Company.

**1 Donald Baker retired as a partner and member of the Executive Committee of Baker & McKenzie, currently the largest law firm in the world. Mr. Baker is also a director of Trimedyne.**

**2 Marvin P. Loeb, Sc.D., is the founder, principal stockholder and Chairman of the Company. He is the inventor or co-inventor of more than fifty (50) U.S. Patents and seven (7) U.S. Patent Applications.**

**Dr. Loeb founded a total of 27 companies in the healthcare and related fields over a period of forty years, three of which were merged together to form Trimedyne. He took Trimedyne and 12 of the other companies public by IPOs, 10 of which were sold to or merged with other companies. Two of these publicly-held companies reached market capitalizations of about \$1.6 billion and \$1.0 billion, respectively, and a few reached market caps of about \$200 to \$300 million, 6 of the privately-held companies were sold to larger companies without going through an IPO, 4 failed (2 public and 2 private) and 2 are privately-held.**

**Dr. Loeb holds a Bachelor's Degree from the University of Illinois and received an honorary Doctor of Science Degree from Pacific State University in Los Angeles in recognition of his many contributions to medicine, including (a) the first drug approved for sale by the FDA to treat the wasting, weakness and loss of muscle tissue of AIDS, marketed by Abbott Laboratories; (b) the three most effective drugs, at that time, to treat certain eye infections, acquired by Bausch & Lomb; (c) the first laser approved for sale by the FDA to vaporize plaque in arteries, marketed by Trimedyne; (d) the first computerized electrocardiogram (ECG) analysis system, acquired by Becton Dickinson; (e) the first laser to effectively treat herniated (bulging) spinal discs, marketed by Trimedyne; (f) the first laser to effectively treat enlarged prostates in men, marketed by C. R. Bard; (g) the first generic oral contraceptive, marketed by G. D. Searle, a subsidiary of Monsanto; and (h) the lowest estrogen content oral contraceptive, marketed worldwide by Organon, a large European pharmaceutical company; and others.**

**3 Glenn D. Yeik has been President and a Director of Trimedyne for more than ten years, prior to which he was Vice President-R&D. Mr. Yeik is a very capable Manager, a skilled Engineer, expert in Regulatory & QA/QC, and highly experienced in Manufacturing and R&D. He is an inventor of 3 U.S. Patents, one Foreign Patent and 4 pending U.S. Patent Applications. He is a son-in-law of Dr. Loeb.**

## Trimedyne's Intellectual Property

### **3 U.S. PATENTS, 6 U.S. PATENT APPLICATIONS AND TRIMEDYNE'S "PRIOR USE"**

(a) U.S. Patent No. 7,492,987, expiring on 12/18/26, covers improvements in the energy transmission efficiency and durability of Side Firing Fibers and Needles (Yeik et al).

(b) U.S. Patent No. 6,740,107, expiring on 12/19/21, covers a Balloon Centered, Side Firing Laser Device, in the event we want to use such a device in our clinical trials or prevent others from doing so (Loeb).

(c) U.S. Patent No. 6,635,052, expiring on 4/11/21, covers a Multifiber Device for delivering laser energy into tissue, in case we want to use such a device in our clinical trials or prevent others from doing so (Loeb).

(d) U.S. Patent 5,989,294, which expires on 12/18/17, covers the use of laser and other sources of thermal energy to modify tissues. We believe this is the first U.S. Patent to be issued covering the use of thermal energy to modify tissues, including shrinkage of tissues. This Patent and Trimedyne's "prior use" of its Holmium Lasers and optical fibers to shrink tissues since 1994 and denervate malfunctioning S/PS Nerves since 1996 constitutes commercial "prior use", and predates by years any patents in this area of which we are aware (acquired).

(e) **A pending U.S. Patent Application covering Lasers and Side Firing Fibers for the denervation of malfunctioning S/PS Nerves of the duodenum or celiac artery to treat Type II Diabetes, and other conditions (Loeb).**

(f) **A pending U.S. Patent Application covering Lasers and Side Firing Fibers for the shrinkage of tissues, such as the pyloric valve of the stomach to treat Obesity or the esophageal valve to treat GERD, and other conditions (Loeb).**

(g) **A pending U.S. Patent Application covering New, Improved Side Firing Laser Devices (Yeik).**

(h) **A U.S. Patent Application in the process of preparation and review by patent counsel prior to filing, covers a fiber-optic device that focuses beams of laser energy to intersect at a desired depth in tissue (Loeb).**

(i) **A U.S. Patent Application in the process of preparation and review by patent counsel prior to filing, covers a fiber-optic device that focuses a beam of laser energy to converge at a desired depth in tissue (Yeik).**

(j) **A U.S. Patent Application in the process of preparation and patent counsel review prior to filing, covers a MiniPulse™ Holmium Laser (Yeik).**

The Company plans to file the six (6) above U.S. Patent Applications in a number of major countries.

There is no assurance any of the above U.S. Patents will be held to be valid if tested in court, any of the above U.S. Patent Applications will issue as U.S. Patents or, if issued, will be held to be enforceable if tested in court, or that patents owned by others will not be successfully enforced against us.

### Incentive Stock Purchase Plan

The Company has established an Incentive Stock Purchase Plan, under which two (2) million Shares are reserved for sale to officers, directors, employees and consultants of the Company to align their interests with those of the Company's shareholders. Such Shares may be sold initially at a price of \$0.01 per Share, after completion of this Offering at a price of \$1.00 per Share and, if a trading market in our Shares arises, at their then fair market value. No Shares have presently been sold under the Incentive Stock Purchase Plan.

The Shares sold to officers, directors, employees or consultants of the Company under the Company's Incentive Stock Purchase Plan, unless otherwise determined by the Company's Board of Directors, will be subject to repurchase by the Company at the issue price, on a pro-rata basis, if the purchaser fails for any reason to remain an officer or employee of the Company throughout each year of a five (5) year period, or fails to remain a Director or consultant of the Company throughout each year of a three (3) year period, following the date of purchase of the Shares. The Company will hold the Certificates for these Shares until they are vested. Any Shares repurchased will be held for sale to present and future officers, directors, employees and consultants of the Company at their then fair market value. In the event of the sale of the Company, the Company's stock repurchase rights will become void.

### **Stock Option Plan**

The Company has authorized the reservation of two (2) million of its Shares for granting of stock options at a price of \$1.00 per share and, if a trading market in our Shares arises, at their fair market value, to its officers, directors, employees and consultants, pursuant to an Incentive and Non-Qualified Stock Option Plan (the "Stock Option Plan"), no options have been granted under the Stock Option Plan.

Under the Directors' segment of our Stock Option Plan, our non-compensated directors are each granted a stock option to purchase 30,000 Shares at their then fair market value on their becoming a Director of the Company and on each anniversary date of their having served as a Director of the Company for three (3) years, and are exercisable over a period of six (6) years from their date of grant.

Options granted under our Stock Option Plan to officers and employees will vest over a period of five years, or to directors and consultants, over a period of three years, and will be exercisable over a period of ten or six years, respectively. In the event the Company is acquired, all unvested stock options will be vested.

## **REGULATORY REQUIREMENTS**

### **Government Regulation**

All of our products are, and will in the future, be subject to extensive governmental regulation and supervision, principally by the Food and Drug Administration ("FDA") and comparable governmental authorities in other countries. The FDA regulates the introduction, advertising, manufacturing practices, labeling and record keeping of all medical devices. The FDA has the power to seize adulterated or misbranded devices, require removal of devices from the market, enjoin further manufacture or sale of devices and publicize relevant facts regarding devices.

Prior to the sale of any of our products, we are required to obtain marketing clearance or approval for each product for its intended uses from the FDA and comparable authorities in foreign countries. Extensive clinical (human) testing of each product, which is both costly and time-consuming, may be required to obtain such approvals. Our business would be adversely affected if we were unable to obtain such approvals or to comply with continuing regulations of the FDA and other governmental agencies. In addition, we cannot predict whether future changes in FDA or foreign government regulations might threaten our existing FDA clearances, make obtaining FDA clearances for new devices more difficult, increase the cost of conducting our business or affect the time required to develop, test and introduce new products. Specific areas of regulation by the FDA and other related matters are described in detail below:

### **Investigational Device Exemption**

Before a new medical device may be used for investigational research (clinical trials) in the United States, an Investigational Device Exemption ("IDE") application must be approved by the FDA, unless the device has already been cleared for sale by the FDA. Also, to obtain an IDE, the sponsor of the investigational research must first obtain approval for the research from the institutional Review Board ("IRB") of the institution (e.g. hospital, clinic, physician practice, etc.) at which the clinical study is to be conducted. Outside the U.S., approval for participating in a clinical study by the institution's "Ethics Committee" is required.

## **510(K) Premarket Notification**

The procedure for obtaining clearance from the FDA to market a new medical device can involve many steps, such as IDE's and PMA's (see "Premarket Approval" below). However, if a device is substantially equivalent to a product marketed prior to May 28, 1976, or is substantially equivalent to a comparable product cleared for sale by the FDA under a 510(k) Premarket Notification, a 510(k) Premarket Notification may be filed to establish the device's equivalence.

The FDA's review process for a 510(k) Premarket Notification can take three months or longer. However, if additional testing or data are requested by the FDA, the overall review process may be extended.

Our current products were cleared for sale in the United States by the FDA pursuant to 510(k) Premarket Notifications. While 510(k) Notifications usually do not require clinical trials, in some cases, 510(k) Notifications may require clinical trials.

## **Premarket Approval (PMA)**

Under the Medical Device Amendments of 1976, all medical devices are classified by the FDA into one of three classes. A "Class I" device is one that is subject only to general controls, such as labeling requirements and good manufacturing practices ("GMP"). A "Class II" device is one for which general controls and performance standards alone are insufficient to secure safety and effectiveness, unless the device qualifies for sale under a 510(k) Premarket Notification. "Class III" devices generally require clinical testing to establish their safety and efficacy in treating specific diseases or conditions, and either a 510(k) Premarket Notification, with or without a clinical trial, or a Premarket Approval ("PMA") with a clinical trial. An application for the intended use of the device must be approved by the FDA before the device can be marketed in the United States. A device is generally classified as a Class I, II or III device based on recommendations of advisory panels appointed by the FDA. Our Lasers and Side Firing Fibers are presently considered Class III devices eligible for marketing under a 510(k) Premarket Notification. However, the FDA can change any Class III device's classification to require a PMA, at any time.

The filing of a PMA Application generally entails one or more expensive, lengthy clinical trials. After completion of the clinical trials, a rigorous review of the data and an inspection of the manufacturing facility and manufacturing process by the FDA can take one year or longer, unless additional testing or data are requested by the FDA, in which case the review process can be considerably longer.

We cannot assure that PMA approvals will not be required by the FDA for our current products or, if PMA approvals are required, that they can be obtained or, if obtained, that they can be maintained. The failure to obtain and maintain PMA approvals for any of our products, if required, could have a material adverse effect upon our future operations.

## **Inspection of Plants**

The FDA also has authority to conduct detailed inspections of manufacturing plants to determine whether or not the manufacturer has followed its GMP requirements, which are required for the manufacture of medical devices. Additionally, the FDA requires reporting of certain product defects and prohibits the domestic sale or exportation of devices that do not comply with the law. We believe Trimedyne is in compliance in all material respects with these regulatory requirements, and we expect that their processes and procedures in place will satisfy the FDA, although we cannot assure that this will be so.

## **State Regulation**

Federal law preempts states or their political subdivisions from regulating medical devices. Upon application, the FDA may permit state or local regulation of medical devices which is either more stringent than federal regulations or is required because of compelling local conditions. To date, and to the best of our knowledge, only California has filed such an application. On October 5, 1980, the FDA granted partial approval

to such application, effective December 9, 1980. The California requirements, which have been exempted from federal law preemption, have not had a materially adverse effect on Trimedyne's manufacture of products to date, but there is no assurance this will not change in the future.

### **Cost of Compliance With FDA and Other Applicable Regulations**

The costs of complying with FDA and other governmental regulations are paid by Trimedyne as the manufacturer of the products, but is ultimately borne by us in the GAAP Cost plus 35% pricing arrangement with Trimedyne.

In the event applicable regulations require more rigorous testing than might otherwise be deemed necessary, the costs of testing the product by unaffiliated institutions (and fees or royalties, if any, payable to them) may be deemed to be part of the cost compliance with such regulatory requirements.

## **REIMBURSEMENT**

To permit the users of our products to obtain reimbursement from insurance companies, health maintenance plans (HMOs) and other third-party payers, such as Medicare, we will be required to demonstrate, in an application to the above parties and the Centers for Medicare and Medicaid Services ("CMS"), which administers the Medicare and Medicaid Programs, at either the federal or state level or both, the safety and efficacy of our products and the benefit to patients therefrom which justify the cost of such reimbursement. There is no assurance that any application for coverage and reimbursement by us will be approved by CMS or other third-party payers. Most private health insurance companies, HMOs, state health care plans and foreign governmental health programs have standards for reimbursement similar to those of CMS and usually follow CMS' coverage decisions. Foreign governmental health programs usually reimburse at a much lower amount than Medicare and other U.S. Third-party payers. If any of our products is refused reimbursement by Medicare, private insurers, HMOs, state health care plans or foreign governmental health programs, sales of such products would be adversely affected.

## **OTHER MATTERS**

### **Employees**

On August 31, 2014, we had five employees, of whom three were employed in administration, one in accounting and one in secretarial, all on a part time basis. Our employees are not subject to any collective bargaining agreements, and we believe our relationship with our employees is good.

We will require additional full and part-time officers, employees and consultants in the areas of administration, product development, clinical trial management, accounting, sales and marketing in the future. There is intense competition for capable, experienced personnel in the medical device field, and we cannot assure that we will be able to obtain experienced, capable officers, employees or consultants when required.

### **Competition**

We face competition from a number of small and large companies in the healthcare field. Among the small companies with which we compete are New Star Lasers, Inc., Convergent Lasers, Inc., Lisa Lasers, Inc., Biolitec, Inc. Dornier Medical, Inc., Laser Peripherals, Inc. and others.

We also compete with large, established companies in the medical field, including Medtronic, Inc., Boston Scientific, Inc., Covidien, Inc., St. Jude Medical, Inc. Lumenis, Ltd. and others, all of which have greater financial resources and larger management, R & D, accounting, sales and marketing organizations than us.

### **Insurance**

Trimedyne has a commercial general liability insurance policy and a products liability insurance policy, each providing coverage per claim and in the aggregate of \$5,000,000. We plan to acquire comparable general liability insurance and products liability insurance. There is no assurance we will be able to acquire such insurance at a reasonable cost or at all.

We do not carry any directors and officers' liability insurance, but our By-Laws contain indemnification provisions covering our officers and directors to the fullest extent permitted by Nevada law.

### **Retirement Plans**

The Company has no retirement plans and carries no key man life insurance on any of its officers, directors or employees. To our knowledge, none of the Company's officers, directors or employees was an executive officer, director or partner in any entity which filed under the Bankruptcy Act or any State insolvency law.

### **Properties**

We currently occupy approximately 300 square feet of modern office space in Trimedyne's office and manufacturing facility in Irvine, CA. at no cost, without a lease. Upon the completion of this Offering, we plan to rent about 5,000 square feet of modern office space near Trimedyne's facility in Irvine, CA.

### **Litigation**

There are presently no lawsuits against us and none are threatened. We may be subject in the future to various lawsuits that may arise in the ordinary course of our business. The litigation process is costly, time consuming and inherently uncertain, and it is possible that the resolution of any future litigation may materially adversely affect our business and financial condition.

### **Executive Compensation**

No person received compensation from us since our organization and we presently have no employment agreements with any of our officers, directors, employees or consultants.

### **Security Ownership Of Management And Others**

We presently have 10,000,000 Shares outstanding, of which 7 million are owned by the Marvin P. Loeb Research Foundation, Inc. and 3 million are owned by Trimedyne, Inc.

The following table sets forth at September 5, 2014, the number of Shares, name and address of each officer, director or beneficial owner of more than five percent of the Company's Common Stock ("Controlling Shareholders") to whom Shares of the Company will be sold by the Company under its Incentive Stock Purchase Plan at a price of \$0.01 per Share, and the total number of Shares to be sold to them as a group.

Name and Address of Beneficial Owner	No. of Shares and Percentage Held on an Outstanding and Fully-Diluted Basis <sup>1</sup>		
	<u>Shares To Be Owned</u>	<u>% of Shares Out- standing<sup>2</sup></u>	<u>% of Shares Fully Diluted<sup>3</sup></u>
<b>Directors and Executive Officers</b>			
Marvin P. Loeb Irrevocable Trust <sup>4</sup> in consideration of Dr. Loeb's serving as Chairman of the Company 5567-A Via Portora Laguna Woods, CA 92637	300,000	1.93%	1.19%
Glenn D. Yeik, President & Director <sup>5</sup> 21831 Eagle Lake Circle Lake Forest, CA 92630	150,000	0.97%	0.60%

Brian T. Kenney, V.P. Clinical Training<sup>6</sup>  
7 Columbus Lane  
Laguna Niguel, CA 92677

30,000 0.19% 0.12%

Donald Baker, Director<sup>7</sup>  
544 Earlston Road  
Kenilworth, IL 60043

30,000 0.19% 0.12%

All Officers and Directors as a group, four persons.

510,000 3.29% 2.02%

- |   |  |
|---|--|
| 1 All Shares are beneficially held.   | 4 Fully vested and assigned to the Loeb Trust.                 |
| 2 Assuming all of the Shares being offered are sold.  | 5 50% vested and 25% vested at the end of years two and three. |
| 3 Assuming all Stock Options and all Shareholder, Underwriter and Additional Underwriter Warrants are exercised and all Shares reserved under the Incentive Stock Purchase Plan are sold. | 6 One-third vested each year over a period of three (3) years. |
|   | 7 Fully vested.  |

### Miscellaneous

In recessions, people put-off medical expenditures, even if they may be to treat serious conditions. If business and economic conditions do not improve, sales of our products will suffer.

Shares of medical device companies, particularly young companies, have been subject to volatility in the market, and involve special risks.

We may be unable to keep our technology in the forefront in our markets, and sales of our products may suffer from technological obsolescence, as the medical field is subject to rapid technological change.

Trimedyne has been in business for 34 years and had a net profit of \$329,000 in its fiscal year ended September 30, 2012. However, Trimedyne has suffered losses in its prior years. If Trimedyne were to fail, we may not be able to secure an alternate supplier of Lasers and Side Firing Fibers with Patents that protect them, the absence of which would severely impact our business.

The loss of our Chairman or President would adversely affect our business, as there is intense competition for talented, experienced managers in the medical device field.

While we have no plans to do so, we may acquire other entities for cash or stock and may incur debt in doing so, even though these entities may entail significant risks and dilution to our shareholders.

### **TRANSACTIONS WITH MANAGEMENT**

There are no transactions with management other than those described in "General", "Management" and "Security Ownership of Management and Others" under "BUSINESS".

### **DESCRIPTION OF SECURITIES**

Our authorized capital stock consists of 75,000,000 shares of \$0.001 par value Common Stock (the "Shares").

## **Common Stock**

Each holder of common stock is entitled to one vote for each share owned on all matters voted upon by stockholders, and a majority vote is required for all actions to be taken by stockholders. In the event we liquidate, dissolve or wind-up our operations, the holders of our common stock are entitled to share equally and ratably in our assets, if any, remaining after the payment of all our debts and liabilities, subject to the liquidation preference of any then outstanding securities senior to the common stock or any secured debt then outstanding.

Holders of our common stock have no preemptive rights and no cumulative voting rights, and no redemption, sinking fund, or conversion provisions. Since the holders of common stock do not have cumulative voting rights, the holders of more than 50% of the outstanding shares of common stock of the Company can elect all of our Directors, and the holders of the remaining Shares, even voting as a group, cannot elect any Directors.

Holders of our common stock are entitled to receive dividends, if and when declared by the Board of Directors out of funds legally available for such purpose.

## **Warrants**

See "THE OFFERING & PLAN OF DISTRIBUTION" for information on the Shareholder Warrants to be issued to the purchasers of Shares of this Offering, and the Selling Dealer Warrants and Additional Selling Dealer Warrants to be issued to the Selling Dealers participating in this Offering, if any, and certain of our officers or directors.

## **Anti-Dilution Rights**

None of our Warrants or Stock Options under our Stock Option Plan have anti-dilution provisions.

## **Reports to Shareholders**

We plan to furnish annual reports to our shareholders, which will include un-audited annual financial statements, or we may post these reports on our website. If prepared, we may also provide un-audited quarterly financial statements and periodic progress reports to shareholders or post them on our website. We are not a reporting company ("Reporting Company") under the Exchange Act of 1934, as amended (the "Exchange Act"), and we are not required to file quarterly or annual reports to our shareholders or proxy statements and other information with the Securities and Exchange Commission ("SEC"). The content of our filings is currently and in the future may not be available on the SEC's website.

We plan to become a Reporting Company under the Exchange Act if a public trading market in our Shares arises, but there is no assurance we will be able to do so or can continue to be a Reporting Company.

## **Transfer Agent**

The Company presently acts as its own transfer agent. If and when a trading market in our Shares arises, which we cannot assure will occur, we plan to appoint American Stock Transfer and Trust Company as the transfer agent and registrar for our Shares. American Stock Transfer and Trust Company is located at 59 Maiden Lane, New York, New York 10038.

## **THE COMMISSION'S POLICY ON INDEMNIFICATION**

Our Certificate of Incorporation contains provisions for the indemnification of our directors and officers to the fullest extent permitted by Nevada law.

Section 78.751 of the Nevada Revised Statutes, as amended, authorizes us to indemnify any director or officer under certain prescribed circumstances and, subject to certain limitations, against certain costs and expenses, including attorneys' fees actually and reasonably incurred in connection with any action, suit or proceeding, whether civil, criminal, administrative or investigative, to which the director is a party by reason of

being our director or a director of our subsidiary, if it is determined that the director acted in accordance with the applicable standard of conduct set forth in those statutory provisions. We may also purchase and maintain insurance for the benefit of any director or officer that may cover claims for which we could not otherwise indemnify him or her.

Insofar as indemnification for liabilities arising under the Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that it is the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable.

### **SHARES AVAILABLE FOR FUTURE SALE**

Shares sold to investors in this Offering can be sold publicly after the Termination Date of this Offering if a trading market in our Shares arises, unless they are purchased by an officer, director or owner of five percent (5%) or more of the Company's Shares, in which event certain holding periods and volume limitations will apply.

Shares owned by the Foundation and Trimedyne, Shares sold by the Company under its Incentive Stock Purchase Plan, even if vested, Shares issued pursuant to the exercise of stock options under its Stock Option Plan, and Shares issued due to the exercise of Selling Dealer Warrants and Additional Selling Dealer Warrants can be sold publicly only after one (1) year from the Termination Date of this Offering, subject to certain holding periods and volume limitations in the case of officers and directors of the Company and owners of five percent (5%) or more of the Company's Shares.

### **TAX CONSEQUENCES**

The Company is a "C" corporation and is not an "S" corporation, a limited liability company or a partnership. As a result, investors in the Shares will have no tax consequences due to the losses or profits, if any, of the Company. However, purchasers of the Shares may have tax consequences from dividends or distributions, if any, or in the event of the merger or acquisition of the Company, the liquidation or dissolution of the Company or in other events.

**PROSPECTIVE INVESTORS IN THE COMPANY SHOULD CONSULT THEIR ACCOUNTANTS AND/OR TAX ADVISORS WITH RESPECT TO ANY POSSIBLE FEDERAL, STATE OR LOCAL TAX CONSEQUENCES WHICH MAY ARISE AS A CONSEQUENCE OF AN INVESTMENT IN THE COMPANY.**

### **LEGAL MATTERS**

In connection with this offering Allen C. Ostergar, III, Esq., has given his legal opinion that we are in good standing in the State of Nevada with due authority to conduct our business, the Shares offered under this Offering Circular have been duly and validly authorized and the Shares will be, when issued, pursuant to Nevada law, fully paid and non-assessable. A copy of this opinion is filed as an Exhibit to the Registration Statement of which this Offering Circular is a part.

### **AVAILABLE INFORMATION**

We are not presently a "Reporting Company" under the Exchange Act of 1934 and are presently not required to file reports, proxy statements or other information with the Securities and Exchange Commission ("SEC"). The content of this Form 1-A Offering Statement may not be available on the SEC's website, and is presently only accessible as described below.

Copies of the material we file with the SEC may be obtained from the Public Reference Room of the SEC, at 100 F Street, N.E., Washington, D.C. 20549 at prescribed rates. The Public Reference Room can be reached at 1-202-942-8090. The SEC also maintains a web site, [www.sec.gov](http://www.sec.gov), that may contain reports, and other information regarding us. However, there is no assurance information on us will be posted on its website.

If a public trading market in our Shares arises, we plan to be a Reporting Company under the Exchange Act of 1934, but our commencing and continuing to do so cannot be assured.

After completion of this Offering, we may become subject to the information requirements of the Securities Act, which may require us to file audited annual reports, unaudited quarterly reports proxy statements and other information with the SEC. Copies of any reports, proxy statements and other information we may then be required to file can be inspected at the Headquarters Office of the Securities and Exchange Commission located at 100 F Street, N.E. Washington, D.C. 20549.

## FINANCIAL STATEMENTS

The following Financial Statements are unaudited and were prepared internally by our management. We believe these Financial Statements contain all adjustments of a recurring nature necessary to fairly present the financial condition of the Company, its results of operations and cash flow for the dates and periods shown.

We were only recently organized, and we have no business or operations. Our only activities prior to our incorporation were more than two (2) years of planning of the use of Trimedyne's Lasers and Fibers in our clinical trials to treat the above-described conditions, preparing and filing two (2) Patent Applications covering the use of Trimedyne's Lasers and Fibers to treat Type II Diabetes, Obesity, GERD and a number of other medical conditions, developing a unique marketing plan and recruiting additional management personnel for the Company (See "BUSINESS").

Following are the Balance Sheet, Profit & Loss Statement and Cash Flow Statement of the Company at the date or for the periods shown.

### BALANCE SHEET at September 15, 2014 (UNAUDITED)

#### ASSETS

##### CURRENT ASSETS

CASH	30,000,000
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##### TOTAL ASSETS

30,000,000

#### LIABILITIES AND STOCKHOLDER'S EQUITY

##### CURRENT LIABILITIES

Accrued Expenses

Total Accrued Expenses	<u>2,000,000</u>
------------------------	------------------

##### TOTAL LIABILITIES

2,000,000

##### STOCKHOLDER'S EQUITY

Common Stock (Par Value \$0.001 per share)	10,000.00
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Additional Paid-in Capital	20,000.00
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Retained Deficit	(2,000.00)
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##### TOTAL STOCKHOLDER'S EQUITY

28,000.00

##### TOTAL LIABILITIES AND STOCKHOLDER'S EQUITY

30,000.00

**PROFIT & LOSS STATEMENT**  
**For The Period From our incorporation on August 31, 2014 to September 12, 2014**  
**(UNAUDITED)**

REVENUES	
Clinical Expenses	2,000
NET LOSS	<u>(2,000)</u>

**CASH FLOW STATEMENT**  
**For the Period from our incorporation on August 31, 2014 to September 12, 2014**  
**(UNAUDITED)**

Cash flows from operating activities:	
Net Loss	\$ (2,000.00)
Adjusts to reconcile net loss to net cash used in operating activities	
Accrued Expenses	<u>2,000.00</u>
Net cash used in operating activities	-
Cash flows from financing activities:	
Proceeds from sale of stock	<u>30,000.00</u>
Net cash provided by financing activities	<u>30,000.00</u>
Net increase in cash	<u>30,000.00</u>
Cash and equivalents at beginning August 28, 2014	-
Cash and equivalents at September 5, 2014	<u>30,000.00</u>

**GASTRODYNE, INC.**  
**Form 1-A Offering Statement**

**PART III**

**PART III**

**INFORMATION NOT REQUIRED IN THE OFFERING CIRCULAR**

**Item 24. Indemnification of Directors and Officers**

Section 78.751 of the Nevada Revised Statutes, as amended, authorizes us to indemnify any of our directors or officers under certain prescribed circumstances and, subject to certain limitations, against certain costs and expenses, including attorneys' fees and costs actually and reasonably incurred in connection with any action, suit or proceeding, whether civil, criminal, administrative or investigative, to which the director or officer is a party by reason of being one of our directors or officers, if it is determined that the director or officer acted in accordance with the applicable standard of conduct set forth in those statutory provisions. Article 12 of our Certificate of Incorporation contains provisions relating to the indemnification of our directors and officers to the fullest extent permitted by Nevada law.

We may also purchase and maintain insurance for the benefit of any director or officer that may cover claims for which we could not indemnify such person.

**Item 25. Other Expenses of Issuance and Distribution**

The following table sets forth the estimated expenses of this Offering, if all of the Shares being offered are sold, as described in the Offering Circular.

Securities and Exchange Commission fee . . . . .	\$ 0
Commissions to Officers and Directors . . . . .	100,000
Legal fees and accounting costs . . . . .	6,000
Blue Sky fees and expenses . . . . .	20,000
Printing and mailing costs . . . . .	4,000
Miscellaneous . . . . .	<u>20,000</u>
TOTAL	\$ 150,000

**Item 26. Recent Sales of Unregistered Securities**

- (a) The Issuer sold in a private transaction on September 3, 2014, an aggregate of 3,000,000 Shares at a price of \$0.01 per Share to Trimedyne, Inc. ("Trimedyne") in connection with Trimedyne's entering into the Private Label Agreement with the Issuer and granting certain rights to the Issuer.
- (b) The Issuer issued at no cost in a private transaction on September 3, 2014 an aggregate of 7,000,000 Shares to the Marvin P. Loeb Research Foundation, Inc., a de jure Nevada corporation in the process of qualification as a 501(c) 4 charitable organization, in consideration of the services of Marvin P. Loeb from May 13, 2012 to August 31, 2014, and his assignment to the Issuer without royalty of certain intellectual property.

With respect to the transactions described in (a) and (b) above, we relied upon the exemption from registration provided by Section 4(2) of the Securities Act of 1933, as amended, as transactions not involving a public offering.

**Item 27. Exhibits**

The following exhibits are filed with this Registration Statement:

		<u>Page No.</u>
2.1	Underwriting Agreement – <b>None.</b>	
2.2	Articles of Incorporation and Business License	III-7
2.3	By Laws	III-13
2.4	Subscription Agreement	III-30
11.0	Opinion of Counsel	III-37
14.0	20 Year, Exclusive, Worldwide, Renewable, Private Label & Distribution Agreement	III-39
15.0	Copies of Publications and News Articles	III-51
16.0	Selling Dealer Agreement	III-67
17.0	Warrant Forms	III-68

**Item 28. Undertakings**

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-qualification amendment to this registration statement to include any material information with respect to any sale of Shares not previously disclosed in the registration statement or any material change to the information in the Offering Statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-qualification amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-qualification amendment any of the securities being registered which remain unsold at the Termination Date of the offering.

(4) The undersigned registrant hereby undertakes that, for the purpose of determining any liability under the Securities Act of 1933, each future filing of any annual report pursuant to section 13 (a) or section 15 (d) of the Securities Exchange Act of 1934 ( and, where applicable, each filing of any employee benefit plan's annual report pursuant to section 15(d) of the Securities Act of 1934) that may be incorporated by reference in the Offering Statement shall be deemed to be a new Offering Statement relating to the securities being offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(5) Insofar as indemnification against liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer, or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

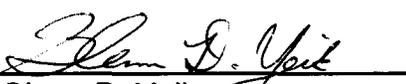
## SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing a Registration Statement on Form 1-A and has duly caused this Registration Statement or Amendment to the Registration Statement on Form 1-A to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Irvine, State of California, on the 15<sup>th</sup> day of Sept., 2014.

GASTRODYNE, INC.

By: Marvin P. Loeb  
Marvin P. Loeb, Sc.D.  
Chairman, CEO and Director

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement or Amendment to the Registration Statement has been signed below by the following persons in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u></u> Marvin P. Loeb, Sc.D.	Chairman, Chief Executive Officer and Director	<u>Sept 15<sup>th</sup></u> , 2014
<u></u> Glenn D. Yeik	President, COO and Director	<u>Sept. 15<sup>th</sup></u> , 2014
<u></u> Alan E. Loeb	Secretary and Treasurer	<u>Sept. 15<sup>th</sup></u> , 2014
<u></u> Donald Baker	Director	<u>Sept. 15<sup>th</sup></u> , 2014

**GASTRODYNE, INC.**  
**Form 1-A Offering Statement**

**EXHIBITS**

**GASTRODYNE, INC.**  
**Form 1-A Offering Statement**  
**Pursuant to Regulation A**

**EXHIBIT 2.2**  
**ARTICLES OF INCORPORATION**

STATE OF NEVADA

ROSS MILLER  
Secretary of State



SCOTT W. ANDERSON  
Deputy Secretary  
for Commercial Recordings

OFFICE OF THE  
SECRETARY OF STATE

Certified Copy

August 28, 2014

**Job Number:** C20140829-0479  
**Reference Number:**  
**Expedite:**  
**Through Date:**

The undersigned filing officer hereby certifies that the attached copies are true and exact copies of all requested statements and related subsequent documentation filed with the Secretary of State's Office, Commercial Recordings Division listed on the attached report.

Document Number(s)	Description	Number of Pages
20140624745-35	Articles of Incorporation	3 Pages/1 Copies



Respectfully,

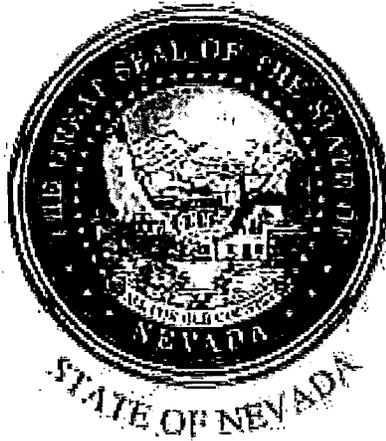
A handwritten signature in black ink, appearing to read "Ross Miller".

ROSS MILLER  
Secretary of State

Certified By: Stephen Loff  
Certificate Number: C20140829-0479  
You may verify this certificate  
online at <http://www.nvsos.gov/>

Commercial Recording Division  
202 N. Carson Street  
Carson City, Nevada 89701-4069  
Telephone (775) 684-5708  
Fax (775) 684-7138

# SECRETARY OF STATE



## CORPORATE CHARTER

I, ROSS MILLER, the duly elected and qualified Nevada Secretary of State, do hereby certify that **GASTRODYNE, INC.**, did on August 28, 2014, file in this office the original Articles of Incorporation; that said Articles of Incorporation are now on file and of record in the office of the Secretary of State of the State of Nevada, and further, that said Articles contain all the provisions required by the law of said State of Nevada.



IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on September 2, 2014.

ROSS MILLER  
Secretary of State

Certified By: Stephen Loff  
Certificate Number: C20140829-0479  
You may verify this certificate  
online at <http://www.nvsos.gov/>



ROSS MILLER  
Secretary of State  
204 North Carson Street, Suite 4  
Carson City, Nevada 89701-4520  
(775) 684-5708  
Website: www.nvsos.gov



\*040104\*

Filed in the office of  Ross Miller Secretary of State State of Nevada	Document Number <b>20140624745-35</b>
	Filing Date and Time <b>08/28/2014 5:55 AM</b>
	Entity Number <b>E0450842014-4</b>

**Articles of Incorporation**  
(PURSUANT TO NRS CHAPTER 78)

USE BLACK INK ONLY - DO NOT HIGHLIGHT

ABOVE SPACE IS FOR OFFICE USE ONLY

<b>1. Name of Corporation:</b>	GASTRODYNE, INC.		
<b>2. Registered Agent for Service of Process:</b> (check only one box)	<input checked="" type="checkbox"/> Commercial Registered Agent: <b>INCORP SERVICES, INC.</b> Name		
	<input type="checkbox"/> Noncommercial Registered Agent (name and address below) <b>OR</b> <input type="checkbox"/> Office or Position with Entity (name and address below)		
	Name of Noncommercial Registered Agent <b>OR</b> Name of Title of Office or Other Position with Entity		
	Street Address _____ City _____ Nevada _____ Zip Code _____ Mailing Address (if different from street address) _____ City _____ Nevada _____ Zip Code _____		
<b>3. Authorized Stock:</b> (number of shares corporation is authorized to issue)	Number of shares with par value: <b>75,000,000</b>	Par value per share: \$ <b>0.001</b>	Number of shares without par value: _____
<b>4. Names and Addresses of the Board of Directors/Trustees:</b> (each Director/Trustee must be a natural person at least 18 years of age; attach additional page if more than two directors/trustees)	1) <b>Marvin P. Loeb</b> Name		
	<b>5567-A Via Portora</b> Street Address	<b>Laguna Woods</b> City	<b>CA 92637</b> State Zip Code
	2) <b>Glenn D. Yeik</b> Name		
	<b>21831 Eagle Lake Circle</b> Street Address	<b>Lake Forest</b> City	<b>CA 92630</b> State Zip Code
<b>5. Purpose:</b> (optional; required only if Benefit Corporation status selected)	The purpose of the corporation shall be:		<b>6. Benefit Corporation:</b> (see instructions) <input type="checkbox"/> Yes
<b>7. Name, Address and Signature of Incorporator:</b> (attach additional page if more than one incorporator)	I declare, to the best of my knowledge under penalty of perjury, that the information contained herein is correct and acknowledge that pursuant to NRS 239.330, it is a category C felony to knowingly offer any false or forged instrument for filing in the Office of the Secretary of State.		
	<b>Marvin P. Loeb</b> Name	<b>X Marvin P. Loeb</b> Incorporator Signature	
	<b>5567-A Via Portora</b> Address	<b>Laguna Woods</b> City	<b>CA 92637</b> State Zip Code
<b>8. Certificate of Acceptance of Appointment of Registered Agent:</b>	I hereby accept appointment as Registered Agent for the above named Entity. <b>X</b> Authorized Signature of Registered Agent or On Behalf of Registered Agent Entity _____ Date _____		

This form must be accompanied by appropriate fees.

Nevada Secretary of State NRS 78 Articles  
Revised: 11-13-13

Additional Page of Section 4:

3) Donald Baker  
Name

544 Earlston Rd.  
Street Address

Kenilworth  
City

IL  
State

60043  
Zip Code



**GASTRODYNE, INC.**  
**Form 1-A Offering Statement**  
**Pursuant to Regulation A**

**EXHIBIT 2.3**

**BY-LAWS**

**BY-LAWS OF  
GASTRODYNE, INC.**

**ARTICLE I  
OFFICES**

Gastrodyne, Inc., a Nevada corporation (the "Corporation"), shall at all times maintain a registered office in the State of Nevada and a registered agent at that address, but may have other offices located within or without the State of Nevada as the Board of Directors may determine.

**ARTICLE II  
SHAREHOLDERS' MEETINGS**

2.1 Annual Meeting. A meeting of holders may, in the discretion of the Directors of the Corporation, be held annually, within five (5) months after the end of each fiscal year of the Corporation. The annual meeting may be held at such time and place and on such date as the directors may determine from time to time and as shall be specified in the notice of the meeting.

2.2 Special Meetings. Special meetings of the shareholders may be called at any time by the Board of Directors, the Chairman of the Board of Directors or any holder or holders of at least twenty-five percent (25%) of the outstanding capital stock of the Company. Special meetings shall be held at such a time and place and on such date as shall be specified in the notice of the meeting.

2.3 Place of Meetings. Annual or special meetings of shareholders may be held within or outside the State of Nevada.

2.4 Notice. Notice of annual or special shareholders' meetings stating the place, day and hour of the meeting shall be given in writing not less than ten (10) nor more than sixty (60) days before the date of the meeting, either mailed to the last known address of such shareholder as shown in the stock records of the Corporation or personally given to the shareholder. Notice of any special meeting of shareholders shall state the purpose or purposes for which the meeting is called. The notice of any meeting at which amendments to or restatements of the Articles of Incorporation, merger or consolidation of the Corporation, or the disposition of corporate assets requiring shareholder approval are to be considered shall state such purpose, and shall further comply with all requirements of law. Notice of a meeting may be waived by an instrument in writing executed before or after the meeting. The waiver need not specify the purpose of the meeting or the business transacted, unless one of the purposes of the meeting concerns a plan of merger or consolidation, in which event the waiver shall comply with the further requirements of law concerning such waivers. Attendance at such meeting in person or by proxy shall constitute a waiver of notice thereof unless the shareholder shall provide written notice to the Corporation prior to the taking of any action by the shareholders at such meeting that his attendance is not to be deemed a waiver of the requirement that such notice be given or of the adequacy of any notice that may have been given to such shareholder.

2.5 Quorum. At all meetings of shareholders, at least 50% of the outstanding shares of stock shall constitute a quorum for the transaction of business, and no resolution or business shall be transacted without the favorable vote of the holders of a majority of the shares represented at the meeting and entitled to vote.

2.6 Proxies; Required Vote. At every meeting of the shareholders, including meetings of shareholders for the election of directors, any shareholder having the right to vote shall be entitled to vote in person or by proxy, but no proxy shall be voted after eleven months from its date, unless said proxy provides for a longer period. Each shareholder shall have one (1) vote for each share of stock having voting power, registered in his name on the books of the Corporation.

2.7 Presiding Officer and Secretary. At every meeting of shareholders, the Chairman of the Board, or in his absence or if there be none, the Vice Chairman of the Board, or in his absence or if there be none, the President, or in his absence, the appointee of the meeting, elected by a majority of the shares present and entitled to vote, shall preside. The Secretary, or in his absence an Assistant Secretary, or if none be present, the appointee of the presiding officer of the meeting, shall act as secretary of the meeting.

2.8 Shareholder List. The officer or agent having charge of the stock transfer books of the Corporation shall produce for inspection of any shareholder at, and continuously during, every meeting of the shareholders, a complete alphabetical list of shareholders arranged by voting group (and within each voting group by class or series of shares) showing the address and share holdings of each shareholder. If the record of shareholders readily shows such information, it may be produced in lieu of such a list.

2.9 Action in Lieu of Meeting. Any action to be taken at a meeting of the shareholders of the Corporation may be taken without a meeting if a consent in writing setting forth all of the actions so taken shall be signed by at least 66.7% of the shareholders of the Corporation and provided that any further requirements of law pertaining to such consents in lieu of a meeting have been complied with.

### ARTICLE III DIRECTORS

3.1 Management. Subject to these by-laws, or any lawful agreement between the shareholders, which conforms to the requirements of these by-laws, the full and entire management of the affairs and business of the Corporation shall be vested in the Board of Directors, which shall have and may exercise all of the powers that may be exercised or performed by the Corporation.

3.2 Number of Directors. The Board of Directors shall consist of not less than two (2) Directors and no more than seven (7) Directors, unless otherwise determined by a majority of the Corporation's then Directors.

3.3 Election of Directors. Directors may be elected annually, at the annual meeting of shareholders or at a special meeting in lieu of the annual meeting of shareholders or by written consent of the holders of shares representing at least 66.7% of the shares outstanding and entitled to vote thereon in lieu of a meeting. The directors shall serve for a term of three (3) years or until their successors are elected, a Chairman of the Board may be appointed by a majority of the entire Board of Directors or by the holders of a majority of the shares of the Corporation.

3.4 Staggered Terms. Directors may be elected to serve in various classes, enabling their terms to be staggered, without the approval of the shareholders, if determined to be necessary at any time to avoid a "take-over" of the Corporation, by a majority of the entire Board of Directors, and such staggered terms shall commence upon such action by a majority of the Board of Directors.

3.5 Anti-Take Over Actions. A "poisoned pill" provision which takes effect if a party acquires 20% or more of the shares of the Corporation or advises the Corporation of its intention to do so, may be instituted at any time, without the approval of shareholders, by a majority of the entire Board of Directors.

3.6 Resignation. Any director may resign at any time either orally at any meeting of the Board of Directors or by so advising in writing the Chairman of the Board, if any, or in the absence of the Chairman of the Board, the President, or by giving written notice to the Corporation. A director who resigns may postpone the effectiveness of his resignation to a future date or upon the occurrence of a future event specified in a written tender of resignation. If no time of effectiveness is specified therein, a resignation shall be effective upon tender. A vacancy shall be deemed to exist at the time a resignation is tendered, and a majority of the Corporation's then remaining directors, or the holder(s) of a majority of the Corporation's voting stock

shall, then or thereafter, elect or appoint a successor to take office when the resignation by its terms becomes effective.

3.7 Compensation. Directors may be allowed such compensation for attendance at regular or special meetings of the Board of Directors and of any special or standing committees thereof as may be determined from time to time by resolution of a majority of the then Board of Directors.

#### ARTICLE IV COMMITTEES

##### 4.1 Executive Committee.

(a) The Board of Directors may, by resolution adopted by a majority of the entire Board of Directors, designate an Executive Committee of two or more directors, one of which shall be the Chairman of the Board of the Corporation, who shall be the Chairman of the Executive Committee. Each member of the Executive Committee shall hold office until his successor is elected and qualified, or until his death, resignation or removal, or until he shall cease to be a director.

(b) During the intervals between the meetings of the Board of Directors, the Executive Committee may exercise all the authority of the Board of Directors; provided, however, that the Executive Committee shall not have the power to amend or repeal any resolution of the Board of Directors that by its terms shall not be subject to amendment or repeal by the Executive Committee, and the Executive Committee shall not have the authority of the Board of Directors in reference to (1) approving or proposing to shareholders action required to be approved by shareholders; (2) filling vacancies on the Board of Directors or on any of its committees; (3) approving the amendment or repealing of the Articles of Incorporation or these by-laws; or (4) a plan of merger, a share exchange on the sale of substantially all of the assets of the Corporation.

(c) The Executive Committee shall meet from time to time on the call of the Chairman of the Board or a majority of the members of the Executive Committee. Meetings of the Executive Committee may be held at such place or places, within or outside the State of Nevada, as the Executive Committee shall determine or as may be specified or fixed in the respective notices or waivers of such meetings. The Executive Committee may fix its own rules of procedures, including provision for notice of its meetings. It shall keep a record of its proceedings and shall report these proceedings to the Board of Directors at the meeting thereof held next after they have been taken or in writing to all of the directors of the Corporation, and all such proceedings shall be subject to revision or alteration by a majority of the entire Board of Directors.

(d) The Executive Committee shall act by majority vote of its members; provided, that contracts or transactions of and by the Corporation in which officers or directors of the Corporation are interested shall require the affirmative vote of a majority of the disinterested members of the Executive Committee, at a meeting of the Executive Committee at which the material facts as to the interest and as to the contract or transaction are disclosed or known to the members of the Executive Committee prior to the vote, written notice which shall, within five (5) days, be provided to the entire Board of Directors, which may rescind, modify, change or revise such actions.

(e) Members of the Executive Committee may participate in committee proceedings by means of conference telephone or similar communications equipment by means of which all persons participating in the proceedings can hear each other and such participation shall constitute presence in person at such proceedings.

(f) The Board of Directors, by resolution adopted in accordance with paragraph (a) of this section, may designate one or more directors as alternate members of the Executive Committee who may act in the place and stead of any absent member or members at any meeting of said committee.

4.2 Other Committees. The Board of Directors, by resolution adopted by a majority of the entire Board, may designate one or more additional committees, each committee to consist of two or more of the directors of the Corporation, which shall have such name or names and shall have and may exercise such powers of the Board of Directors, except the powers denied to the Executive Committee, as may be determined from time to time by the Board of Directors. Such committees shall provide for their own rules of procedure, subject to the same restrictions thereon as provided above for the Executive Committee.

4.3 Removal. A majority of the entire Board of Directors shall have power at any time to remove any member of any committee, except the Chairman of the Board, with or without cause, and to fill vacancies in and to dissolve any such committee.

## ARTICLE V MEETINGS OF THE BOARD OF DIRECTORS

5.1 Time and Place. Meetings of the Board of Directors may be held at any place either within or outside the State of Nevada. Each newly elected Board of Directors shall meet immediately following the close of the annual meeting of shareholders and at the place thereof, if any, or at the call of the holders of a majority of the then outstanding voting shares of the Corporation, or such newly elected Board of Directors may hold such meeting at such place and time as shall be fixed by the consent in writing of all the then directors. In any such case no notice of such meeting to the newly elected directors shall be necessary in order legally to constitute the meeting. If the Board of Directors is elected by written consent of shareholders without a meeting, then the newly elected Board shall meet as soon as is reasonably practicable after such consent is duly filed with the Corporation, at the call of the Chairman of the Board, if any, of the President or of a majority of the directors then in office, at such time and place as shall be specified by written notice thereof given to each director at least ten (10) days before the meeting, said notice containing all of the actions to be considered by the directors at such meeting.

5.2 Regular Meetings. Regular meetings of the Board of Directors may be held without notice at such time and place, within or outside the State of Nevada, as shall be determined by a majority of the entire Board of Directors from time to time.

5.3 Special Meetings; Notice. Special meetings of the Board of Directors may be called by the Chairman of the Board or, if none, by the President, on not less than five (5) day's written notice by email or facsimile transmission to each director and shall be called by the Chairman of the Board or, if none, the President, in the manner provided in Paragraph 5.1 above and on like notice on the written request of a majority of the entire Board of Directors. Any such special meeting shall be held at such time and place, within or outside the State of Nevada, as shall be stated in the notice of meeting.

5.4 Waiver of Notice. Notice of any meeting of the Board of Directors may be waived by an instrument in writing executed by the attendees before or after the meeting. Attendance in person at any such meeting shall constitute a waiver of notice thereof.

5.5 Quorum. At all meetings of the Board of Directors, the presence of two-thirds (2/3) of the then directors shall be necessary and sufficient to constitute a quorum for the transaction of business. Directors may participate in any meeting by means of conference telephone or similar communications equipment by means of which all persons participating in the meeting can hear each other and participation in a meeting by means of such communication shall constitute presence in person at such meeting. The act of a majority of all of the Directors then in office shall be the act of the Board of Directors, except as may

otherwise specifically provided by law, the Articles of Incorporation, a Shareholder's Agreement or these by-laws.

5.6 Action in Lieu of a Meeting of the Board. Any action required or permitted to be taken at any meeting of the Board of Directors or of any committee thereof may be taken without a meeting if a unanimous written consent of all of the directors then in office, setting forth the actions so taken is signed by all of the directors or members of such committee then in office, as the case may be, and such unanimous written consent is delivered to the Corporation for filing with the minutes of the proceedings of the Board of Directors or of such committee and any further requirements of law pertaining to such consents have been complied with. Such consents may be in identical counterparts of the same document.

5.7 Interested Directors and Officers. An interested director or officer is one who is a party to a contract or transaction with the Corporation or who is an officer or director of, or has a financial interest in, another corporation, partnership, association or other entity which is a party to a contract or transaction with the Corporation. Contracts and transactions between the Corporation and one or more interested directors or officers shall not be void or voidable solely because of the involvement or vote of such interested persons as long as (i) the contract or transaction is approved in good faith by a majority of the entire Board of Directors or appropriate committee by the affirmative vote of a majority of disinterested directors, even if the disinterested directors be less than a quorum, at a meeting of the Board or committee at which the material facts as to the interest of the interested person or persons and the contract or transaction are disclosed or known to the Board or committee prior to the vote; or (ii) the contract or transaction is approved in good faith by the shareholders after the material facts as to the interest of the interested person or persons and the contract or transaction have been disclosed to them; or (iii) the contract or transaction is fair as to the Corporation as of the time it is authorized, approved or ratified by the Board, committee, or shareholders. Interested directors may be counted in determining the presence of a quorum at a meeting of the Board or committee which authorizes the contract or transaction, or by the unanimous written consent of all of the directors then in office, as provided in Paragraph 5.6 above.

## ARTICLE VI OFFICERS, AGENTS AND EMPLOYEES

6.1 General Provisions. The officers of the Corporation shall consist of a Chairman of the Board, a President, a Treasurer and a Secretary, and may include a Chief Executive Officer, Chief Financial or Accounting Officer, a Vice Chairman of the Board, one or more Executive Vice Presidents, Senior Vice Presidents and Vice Presidents, one or more Assistant Treasurers and one or more Assistant Secretaries. The officers shall be elected by the Board of Directors at the first meeting of the Board of Directors or shall be appointed as provided in these by-laws. The Board of Directors may elect other officers, agents and employees, who shall have such authority and perform such duties as may be prescribed by the Board of Directors. All officers shall hold office until the meeting of the Board of Directors following the next annual meeting of the shareholders after their election or appointment and until their successors shall have been elected or appointed and shall have qualified, unless their terms are longer, as determined by a majority of the entire Board of Directors. Any two or more offices may be held by the same person. Any officer, agent or employee of the Corporation may be removed by the action of a majority of the directors then in office or, in the case of the Chairman of the Board, by 66.7% of the directors then in office, with or without cause. Such removal without cause shall be without prejudice to such person's contract rights, if any, but the election or appointment of any person as an officer, agent or employee of the Corporation shall not of itself create contract rights. The salary guidelines for compensation of officers shall be fixed by the Board of Directors, but this power may be delegated to the Chairman of the Board or any officer, agent or employee acting under his direction or control. The Board of Directors may require any officer, agent or employee to give security for the faithful performance of his duties. Compensation of department heads, managers and other employees shall be determined in good faith by the Chairman, President, CEO or COO, if any.

6.2 Powers and Duties of the Chairman of the Board, the Vice Chairman of the Board and the President. The powers and duties of the Chairman of the Board, the Vice Chairman of the Board, if any, and the President, subject to the supervision and control of the Board of Directors, shall be those usually appertaining to their respective offices and whatever other powers and duties are prescribed by these by-laws or by a majority of the entire Board of Directors.

(a) The Chairman of the Board shall call and preside at all meetings of the Board of Directors and at all meetings of the shareholders.

(b) The Vice Chairman of the Board, if any, or the President shall, in the absence or disability of the Chairman, perform the duties of the Chairman.

(c) The Chief Executive Officer (CEO) shall, unless otherwise provided by the Board of Directors, be the chief executive officer of the Corporation. He shall have general charge of the business and affairs of the Corporation and shall keep the Board of Directors fully advised. He shall employ and discharge officers, employees or agents of the Corporation, other than the Chairman or Vice Chairman of the Board of Directors, if any, but he may not delegate these powers. He shall have such powers and perform such duties as generally pertain to the office of the President, as well as such further powers and duties as may be prescribed by the Board of Directors.

(d) The Chairman of the Board, the CEO, if any, or, if none, the President may vote the shares or other securities of any other domestic or foreign corporation of any type or kind which may at any time be owned by the Corporation, may execute any shareholders' or other consents in respect thereof and may in his discretion delegate such powers by executing proxies, or otherwise, on behalf of the Corporation. He may endorse all commercial documents requiring endorsements for or on behalf of the Corporation and may sign all receipts and all commercial documents requiring endorsements for or on behalf of the Corporation and may sign all receipts and vouchers for payments made to the Corporation, unless they constitute matters which should reasonably be brought to the attention of the Chairman of the Board and receive his approval, prior to his signing any of the above. He may execute long term agreements, commitments and purchases or leases of real property of the Corporation, subject to prior approval of a majority of the entire Board of Directors.

6.3 Limits on Authority of Officers & Directors. Without the express prior written consent of a majority of the directors then in office, no officer or director of the Corporation shall have authority to:

- (a) Do any act in contravention of these by-laws or a Shareholder's Agreement, if any, as amended;
- (b) Do any act which would make it impossible to carry on the ordinary business of the Corporation;
- (c) Comingle Corporation funds with funds of any person(s) or entity;
- (d) Confess a judgment against the Corporation;
- (e) Sell any property of the Corporation, lease, pledge, hypothecate, grant a security interest or assign rights in such property, other than in the ordinary course of business;
- (f) Merge or consolidate the Corporation with or into any other person or entity or change or reorganize the Corporation into any other legal form;
- (g) Attempt to dissolve the Corporation, except as provided in these by-laws;

- (h) Execute or deliver any general assignment for the benefit of creditors of the Corporation or permit the entry of an order of relief against the Corporation under the Federal Bankruptcy Code or any equivalent state statute;
- (i) Pledge the credit of the Corporation for any purpose except for the Corporation's purposes in the ordinary conduct of its business;
- (j) Change the business of the Corporation from that stated in these by-laws; or
- (k) Sell or transfer all, substantially all or a substantial amount of the assets of the Corporation.

6.4 Powers and Duties of Vice Presidents. Each Executive Vice President, Senior Vice President and Vice President shall have such powers and perform such duties as the Chairman of the Board of Directors or the CEO may prescribe and shall perform such other duties as may be prescribed by these by-laws. In the absence or inability to act of the Chairman of the Board or CEO, unless the Board of Directors shall otherwise provide, the President shall perform all duties and may exercise any of the powers of the CEO.

6.5 Powers and Duties of the Treasurer. The Treasurer or Assistant Treasurer shall have charge of all funds and securities of the Corporation and shall endorse the same for deposit or collection when necessary and deposit the same to the credit of the Corporation in such banks or depositories as the Board of Directors may authorize. He shall have all such powers and duties as generally are incident to the position of corporate treasurer or as may be assigned to him by the Chairman or CEO or, in their absence or inability to act, by President or a majority of the entire Board of Directors.

6.6 Powers and Duties of the Secretary. The Secretary or Assistant Secretary shall have charge of the minutes of all proceedings of the shareholders and of the Board of Directors and shall keep the minutes of all their meetings at which he is present. Except as otherwise provided by these by-laws, he shall attend to the giving of all notices to shareholders and directors. He shall have charge of the seal of the Corporation, shall attend to its use on all documents the execution of which on behalf of the Corporation under its seal is duly authorized by the Board of Directors, and shall attest the same by his signature whenever required. He shall have charge of the record of shareholders of the Corporation, of all written requests by shareholders that notices be mailed to them at an address other than their addresses on the record of shareholders, and of such other books and papers as the Board of Directors may direct. Subject to the control of the Chairman or the Board of Directors, he shall have all such powers and duties as generally are incident to the position of corporate secretary or assistant secretary or as may be assigned to him by the Chairman or CEO or, in their absence or inability to act, President or the Board of Directors.

6.7 Delegation of Duties. In case of the absence of any officer of the Corporation, or for any other reason that a majority of the entire Board of Directors may deem sufficient, the Board of Directors (or in the case of Assistant Secretaries or Assistant Treasurers only, the Chairman, or in his absence, the CEO or President) may confer for the time being the powers and duties, or any of them, of such officer upon any other officer (provided that the powers and duties of the Chairman or, in his absence, the CEO or President may not be conferred upon the Secretary, and vice versa), or elect or appoint any new officer to fill a vacancy created by death, resignation, retirement or termination of the Secretary or any Assistant Secretary. In such latter event such new Secretary or Assistant Secretary shall serve until the next annual election of officers, unless any of them are earlier terminated by the Chairman or, in his absence, the CEO or President.

## ARTICLE VII CAPITAL STOCK

7.1 Certificates. The interest of each shareholder shall be evidenced by a certificate or certificates representing shares of the Corporation which shall be in such form as the Board of Directors may from time to time adopt and shall be numbered and shall be entered in the books of the Corporation as they are issued. Each certificate representing shares shall set forth upon the face thereof the following:

- (a) the name of this Corporation;
- (b) that the Corporation is organized under the laws of the State of Nevada;
- (c) the name or names of the person or entity to whom the certificate is issued;
- (d) the number and class of shares, and the designation of the series, if any, which the certificate represents;
- (e) if any shares represented by the certificate are non-voting shares, a statement or notation to that effect; and, if the shares represented by the certificate are subordinate to shares of any other class or series with respect to dividends or amounts payable on liquidation, shall further set forth on either the face or back of the certificate a clear and concise statement to that effect.

Each certificate shall be signed by the Chairman, CEO or President and the Secretary or an Assistant Secretary and may be sealed with the seal of the Corporation or a facsimile thereof if a certificate is countersigned by a transfer agent or registered by a registrar, other than the Corporation itself or an employee of the Corporation, the signature of any such officer of the Corporation may be a facsimile.

7.2 Shareholder List. The Corporation shall keep or cause to be kept a record of the shareholders of the Corporation which readily shows, in alphabetical order or by alphabetical index, by voting group and, within each voting group, by classes or series of stock, if any, the names of the shareholders entitled to vote, with the address of and the number of shares held by each. Said record shall be presented and kept available at all meetings of the shareholders.

7.3 Transfers of Shares. Transfers of stock shall be made on the books of the Corporation only by the person named in the certificate, or by power of attorney lawfully constituted in writing, and upon surrender of the certificate thereof, or in the case of a certificate alleged to have been lost, stolen or destroyed, upon compliance with the provisions of Section 7.7 of these by-laws.

### 7.4 Record Dates.

(a) For the purpose of determining shareholders entitled to notice of or to vote at any meeting of shareholders or any adjournment thereof, or entitled to receive payment of any dividend, or in order to make a determination of shareholders for any other proper purpose, the Board of Directors may provide that the stock transfer books shall be closed for a stated period but not to exceed seventy (70) days. If the stock transfer books shall be closed for the purpose of determining shareholders entitled to notice of or to vote at a meeting of shareholders, such books shall be closed for at least ten (10) days immediately preceding such meeting.

(b) In lieu of closing the stock transfer books, the Board of Directors may fix in advance a date as the record date for any such determination of shareholders, such date to be not more than seventy (70)

days and, in case of a meeting of shareholders, not less than ten (10) days, prior to the date on which the particular action requiring such determination of the shareholders is to be taken.

7.5 Registered Owner. The Corporation shall be entitled to treat the holder of record of any share of stock of the Corporation as the person entitled to vote such share, to receive any dividend or other distribution with respect to such share, and for all other purposes and accordingly shall not be bound to recognize any equitable or other claim or interest in such share on the part of any other person, whether or not it shall have express or other notice thereof, except as otherwise provided by law.

7.6 Transfer Agent and Registrars. The Board of Directors may appoint one or more transfer agents and one or more registrars and may require each stock certificate to bear the signature or signatures of a transfer agent or a registrar or both.

7.7 Lost Certificates. Any person claiming a certificate of stock to be lost, stolen or destroyed shall make an affidavit or affirmation of the fact in such manner as the Board of Directors may require and shall, if the directors so require, give the Corporation a bond of indemnity in form and amount and with one or more sureties satisfactory to the Board of Directors, whereupon an appropriate new certificate may be issued in lieu of the certificate alleged to have been lost, stolen or destroyed.

7.8 Fractional Shares or Scrip. The Corporation shall not issue certificates for fractional shares or scrip in order to affect share transfers, share distributions or reclassifications, mergers, consolidations or reorganizations. Fractional shares shall be rounded to the next higher or lower share number.

## **ARTICLE VIII BOOKS AND RECORDS; SEAL; ANNUAL STATEMENTS; EXPENSES**

### **8.1 Inspection of Books and Records.**

(a) Any person who is the holder of record of, or authorized in writing by the holders of record of, more than twenty-five percent (25%) of the outstanding shares of any class or series of the Corporation, upon at least five (5) days prior written demand stating the purpose thereof, shall have the right to inspect, in person or by agent or attorney, at any reasonable time or times during the Corporation's usual business hours, excerpts from minutes of any meeting of the Board of Directors, records of any action of a committee thereof while acting in place of the Board of Directors on behalf of the Corporation, minutes of any meeting of shareholders, and records of action taken by the shareholders or Board of Directors without a meeting, accounting records of the Corporation, and the record of shareholders.

(b) A shareholder owning twenty-five percent (25%) of the outstanding shares of the Corporation, as described in Sub-paragraph (a) above, may inspect and copy the records described in the immediately preceding paragraph only if (1) his demand is made in good faith and for a proper purpose that is reasonably relevant to his legitimate interest as a shareholder; (2) he describes with reasonable particularity in writing his purpose and the records he desires to inspect; (3) the records are directly connected with his purpose; (4) the records are to be used only for the stated purpose; and provided at least five (5) days prior written notice of his intent to do so is delivered to the Corporation.

(c) If the Chairman or, in his absence, the CEO or President finds the request proper, he shall direct the Secretary or Assistant Secretary to promptly notify the shareholder of the time and place at which the inspection may be conducted.

(d) If said request is found by the Chairman or, in his absence, the CEO or President not to be proper, he or she shall promptly give written notice to the requesting shareholder on or prior to the date on

which the shareholder requested to conduct the inspection, and shall specify in said notice the basis for the rejection of the shareholder's request.

(e) The Chairman or, in his absence, the CEO or President shall at all times be entitled to rely on these by-laws or the corporate records in making any determination hereunder.

8.2 Seal. The corporate seal shall be in such form as the Board of Directors may from time to time determine. In the event it is inconvenient to use such a seal at any time, the signature of the Corporation followed by the word "Seal" enclosed in parentheses or scroll shall be deemed the seal of the Corporation.

8.3 Annual Statements. Not later than five (5) months after the close of each calendar year, and in any case prior to the next annual meeting of shareholders, unless otherwise determined by the Chairman, or in his absence, the CEO or President or the holder(s) of a majority of the voting shares of the Corporation, the Treasurer shall prepare:

(a) A balance sheet showing in reasonable detail the financial condition of the Corporation as of the close of its year;

(b) A profit and loss statement showing the results of its operations during the immediately past fiscal year or any quarter or quarters thereof. Upon written request, the Corporation promptly shall mail to any shareholder of record a copy of the most recent such balance sheet and profit and loss statement; and

(c) Such other financial statements, documents and reports as may be required by law. A copy of the Corporation's Annual Report containing such financial information or the corporation's 10K Report to the SEC, emailed or mailed to the shareholder or accessible by a link on the Corporation's website or from the SEC shall suffice as a proper answer to (a)-(c) above.

8.4 Expenses. Expenses incurred by any person who was or is a party or who is threatened to be made a party to any threatened, pending, or completed action, suit, or proceeding, whether civil, criminal, administrative, or investigative, and whether formal or informal, by reason of the fact that he is or was a director, officer, employee, or agent of the Corporation or is or was serving at the request of the Corporation as a director, officer, employee, or agent of another corporation, partnership, joint venture, trust, or other enterprise, in defending any civil, criminal, administrative or investigative action, suit or proceeding shall be indemnified by the Corporation to the fullest extent allowed by law, and such cost may be paid by the Corporation in advance of the final disposition of such action, suit or proceeding, as authorized by the Board of Directors generally or as to a specific case or as to a specific person or persons (designated by name, title or class of persons) subject to and upon receipt of an agreement or undertaking by or on behalf of the director, officer, employee or agent, to repay such amount if it shall ultimately be determined that he is not entitled to be indemnified by the Corporation as authorized under the applicable provisions of the Nevada or California Business Corporation Code, or as a majority of the entire Board of Directors shall determine, and upon compliance with any further requirements of law pertaining to such advances.

8.5 Non-exclusivity. The indemnification provided by Section 8.4 shall not be deemed exclusive of any other rights, in respect of indemnification or otherwise, to which those seeking indemnification may be entitled under any bylaw or resolution approved by the affirmative vote of the holders of a majority of the shares entitled to vote thereon taken at a meeting the notice of which specified that such bylaw or resolution would be placed before the shareholders, both as to action by a director, officer, employee or agent in his official capacity and as to action in another capacity while holding such office or position, provided such indemnification does not exceed the powers of indemnity permitted to corporations under the provisions of the Nevada or California Business Corporation Code, as the Board of Director's shall determine, and shall continue as to a person who has ceased to be a director, officer, employee or agent and shall inure to the benefit of the heirs, executors and administrators of such a person.

**ARTICLE IX  
NOTICES; WAIVERS OF NOTICE**

9.1 Notices. Except as otherwise specifically provided in these by-laws, whenever under the provisions of these by-laws notice is required to be given to any shareholder, director or officer, it shall not be construed to mean personal notice, but such notice may be given by (i) personal notice, (ii) courier (e.g. FedEx), (iii) confirmed facsimile transmission, or (iv) U.S. mail addressed to such shareholder, officer or director at such address as appears on the books and records of the Corporation. Notices may also be given by confirmed email, that is an email from the recipient (to the Company or any third party) either containing the notice email or referring or otherwise acknowledging the notice email. All notices shall be deemed to be given at the time when the same shall be sent by personal delivery, facsimile transmission or email.

9.2 Waivers of Notice. Except as otherwise provided in these by-laws, when any notice whatever is required to be given by law, by the Articles of Incorporation or by these by-laws, a written waiver thereof, signed by the person entitled to notice, whether before or after the time stated therein, shall be deemed equivalent to notice. In the case of a shareholder, such waiver of notice may be signed by the shareholder's attorney or proxy duly appointed in writing.

**ARTICLE X  
EMERGENCY POWERS**

10.1 By-laws. The Board of Directors may adopt emergency by-laws, subject to repeal or change by action of the holders of a majority of the shares of the Corporation, which shall, notwithstanding any provision of law, the Articles of Incorporation or these by-laws, be operative during any emergency in the conduct of the business of the Corporation resulting from any catastrophic event including, without limitation, an attack on the United States or on a locality in which the Corporation conducts its business or customarily holds meeting of its Board of Directors or its shareholders, or during any war, insurrection, riot or nuclear or atomic disaster, or during the existence of any catastrophe of nature or otherwise, or other similar emergency condition, as a result of which a quorum of the Board of Directors or a standing committee thereof cannot readily be convened for action. The emergency by-laws shall govern any provision that may be practical and necessary for the circumstances of the emergency.

10.2 Lines of Succession. The Board of Directors, either before or during any such emergency, may provide, and from time to time modify, lines of succession in the event that during such an emergency any or all officers or agents of the Corporation shall for any reason be rendered unavailable or otherwise incapable of discharging their duties.

10.3 Head Office. The Board of Directors, either before or during any such emergency, may effective in the emergency, change the head office or designate several alternative head offices or regional offices, or authorize the officers to do so.

10.4 Period of Effectiveness. To the extent not inconsistent with any emergency by-laws so adopted, these by-laws shall remain in effect during any such emergency and upon the termination of the emergency, the emergency by-laws shall cease to be operative.

10.5 Notices. Unless otherwise provided in emergency by-laws, notice of any meeting of the Board of Directors during any such emergency may be given only to such of the directors as it may be practical to reach at the time, and by such means as may be practical at the time.

10.6 Liability of Officers, Directors and Agents. No officer, director, agent or employee acting in accordance with any emergency by-laws shall be liable, except for willful misconduct. No officer, director,

agent or employee shall be liable for any action taken by him in good faith in such an emergency in furtherance of the ordinary business affairs of the Corporation even though not authorized by the by-laws then in effect, provided such action does not financially benefit the person taking such action.

## **ARTICLE XI CHECKS, NOTES, DRAFTS, ETC.**

Checks, notes, drafts, acceptances, bills of exchange and other orders or obligations for the payment of money shall be signed by the Chairman, unless the Chairman designates the Chief Executive Officer, the President, the Treasurer or the Chief Financial Officer (i.e. any of them individually) or such other officer or officers or person or persons as the Board of Directors by resolution shall from time to time designate, except for checks, wire transfers, notes, drafts, acceptances, bills of exchange and other orders or obligations for the payment of money exceeding U.S. \$25,000, which must be signed by any two (2) of the above, acting in good faith.

## **ARTICLE XII INDEMNIFICATION**

12.1 Definitions. As used in this Article, the term:

(a) "Corporation" means the Corporation and includes any domestic or foreign predecessor entity of the Corporation in a merger or other transaction in which the predecessor's existence ceased upon consummation of the transaction, and any domestic or foreign entity that is the successor to all or substantially all of the business or assets of the Corporation, as a result of merger, consolidation, sale, liquidation or otherwise.

(b) "Director" means an individual who is or was a director of the Corporation or an individual who, while a director of the Corporation, is or was serving at the Corporation's request as a director, officer, partner, trustee, employee, or agent of another foreign or domestic corporation, partnership, joint venture, trust, employee benefit plan, or other enterprise; and shall include, unless the context requires otherwise, the estate or personal representative of a director. An officer of the Corporation requested by the Board of Directors or the Chairman, CEO or President to serve as a director, officer or signer for the Corporation on an employee benefit plan may serve as requested, in good faith and subject to the other fidelity requirements of these by-laws, to the plan or to participants in or beneficiaries of the plan.

(c) "Expenses" include, without limitation, attorney's fees and disbursements, court and arbitration costs and expert witness fees.

(d) "Indemnified Person" means any person entitled to indemnification or advancement of Expenses under this Article Twelve, including, without limitation, pursuant to Sections 12.8 and 12.9.

(e) "Liability" means the obligation to pay a judgment, settlement, penalty, fine (including an excise tax assigned with respect to an employee benefit plan), or reasonable expenses incurred with respect to a proceeding.

(f) "Officer" means an individual who is not a director and who is or was an officer of the Corporation or an individual who, while an officer of the Corporation, is or was serving at the Corporation's request as a director, officer, partner, trustee, employee, or agent of another foreign or domestic corporation, partnership, joint venture, trust, employee benefit plan, or other enterprise; and shall include, unless the context requires otherwise, the estate or personal representative of an officer. An officer is considered to be serving an employee benefit plan at the Corporation's request if his duties to the Corporation also impose duties on, or otherwise involve services by, him to the plan or to participants in or beneficiaries of the plan.

(g) "Party" includes an individual who was, is, or is threatened to be made a named defendant or respondent in a proceeding.

(h) "Proceeding" means any threatened, pending, or completed action, suit or proceeding, whether civil, criminal, administrative, or investigative and whether formal or informal.

#### 12.2 Basic Indemnification.

(a) Indemnification. Except as provided in Section 12.5 and in the Corporation Code of Nevada, or California in the event any officer or director is made a party to a proceeding because he or she was an officer or director, the Corporation shall indemnify such officer or director against liability incurred by him or her in the proceeding to the fullest extent permitted by Nevada or California law, as determined by a majority of the entire Board of Directors, subject to the limitations of Paragraph 8.4 hereof.

(b) Employee Benefit Plans. An officer's or director's conduct with respect to an employee benefit plan is conduct that satisfies the requirement of Paragraph 12.2(a) hereof.

12.3 Mandatory Indemnification. To the extent that any officer or director has been successful, on the merits or otherwise, in the defense of any proceeding to which he or she was a party, or in defense of any claim, issue or matter therein, because he or she is or was an officer or director, the Corporation shall indemnify such officer or director against reasonable expenses incurred by him or her in connection therewith, subject to the requirements of Paragraph 12.2(a) hereof.

#### 12.4 Advances for Expenses.

(a) Deliveries by Indemnified Person. The Corporation shall promptly pay for or reimburse the reasonable expenses incurred by an officer or director as a party to a proceeding in advance of final disposition of the proceeding if:

(i) he or she furnishes the Corporation a written affirmation of his or her good-faith belief that he or she has met the applicable standards of conduct set forth in this Article Twelve; and

(ii) he or she furnishes the Corporation a written undertaking (meeting the qualifications set forth below in subsection 12.4(b)), executed personally or on his or her behalf, to repay any advances if it is ultimately determined that he or she is not entitled to such indemnification under this Article Twelve or otherwise.

(b) Scope of Undertaking. The undertaking required by Paragraph 12.4(a)(ii) above must be an unlimited general obligation of such officer or director but may need not be secured and may be accepted without reference to financial ability to make repayment, if approved in advance by a majority of the entire Board of Directors.

12.5 Limitations on Indemnification. Nothing in this Article Twelve shall require or permit indemnification of an officer or director for any liability in which the officer or director is adjudged liable to the Corporation or is subjected to injunctive relief in favor of the Corporation:

(a) For any appropriation, in violation of his or her duties, of any business opportunity of the Corporation;

(b) For acts or omissions which involve intentional misconduct.

(c) For the types of liability set forth in Section 14-2-832 of the Nevada or California Corporation Code; or

(d) From any transaction from which he or she received an improper personal benefit.

12.6 Court-Ordered Indemnification and Advances for Expenses. An officer or director who is a party to a proceeding may apply for indemnification or advances for expenses to the court conducting the proceeding or to another court of competent jurisdiction. On receipt of an application, the court, after giving any notice the court considers necessary, may order indemnification or advances for expenses if it determines that:

(a) The officer or director is entitled to mandatory indemnification under Section 8.3 above, in which case the Corporation shall also pay such officer or director reasonable expenses incurred to obtain court-ordered indemnification; or

(b) The officer or director is fairly and reasonably entitled to indemnification in view of all the relevant circumstances, subject to Paragraph 12.5 hereof.

(c) In the case of advances for expenses, an officer or a director is entitled pursuant to the Articles of Incorporation, these by-laws or any applicable resolution or agreement, to payment or reimbursement of his or her reasonable expenses incurred as a party to a proceeding in advance of final disposition of the proceeding.

12.7 Witness Fees. Nothing in this Article shall limit the Corporation's power to pay or reimburse expenses incurred by an officer or director in connection with his or her appearance as a witness in a proceeding at a time when he or she has not been made a named defendant or respondent to the proceeding.

12.8 Indemnification of Others. The Board of Directors shall have the power to cause the Corporation to provide to directors, officers, employees and agents of the Corporation all or any part of the right to indemnification permitted for such persons by appropriate provisions of the Nevada or California Corporation Code. Persons to be indemnified may be identified by position or name, and the right of indemnification may be different for each of the persons identified. Each person so identified shall be an "Indemnified Person" for purposes of the provisions of this Article Twelve.

12.9 Other Organizations. The Board of Directors shall have the power to cause the Corporation to provide to any officer, employee or agent of the Corporation who is or was serving at the Corporation's request as a director, officer, partner, trustee, employee, or agent of another corporation, partnership, joint venture, trust, employee benefit plan, or other enterprise all or any part of the right to indemnification and other rights of the type provided under Sections 12.2, 12.3, 12.4, 12.15 and 12.19 of this Article Twelve (subject to the conditions, limitations, and obligations specified in those Sections) permitted for such persons by appropriate provisions of the Corporation Code. Persons to be indemnified may be identified by position or name, and the right of indemnification may be different for each of the persons identified. Each person so identified shall be an "Indemnified Person" for purposes of the provisions of this Article Twelve.

12.10 Non-Exclusivity. Subject to any applicable limitation imposed by the Corporation Code or the Articles of Incorporation, the indemnification and advancement of expenses provided by or granted pursuant to this Article Twelve shall not be exclusive of any other rights to which a person seeking indemnification or advancement of expenses may be entitled under any provision of the Articles of Incorporation, or any bylaw, resolution or agreement specifically or in general terms approved or ratified by the affirmative vote of holders of a majority of the shares of the Corporation entitled to be voted thereon.

12.11 Insurance. The Corporation shall have the power to purchase and maintain insurance on behalf of any person who is or was a director, officer, employee, or agent of the Corporation, or who, while serving in such a capacity, is also or was also serving at the request of the Corporation as a director, officer, trustee, partner, employee, or agent of any corporation, partnership, joint venture, trust, employee benefit plan, or other enterprise, against any liability that may be asserted against or incurred by him or her in any such capacity, or arising out of his or her status as such, whether or not the Corporation would have the power to indemnify him or her against such liability under the provisions of this Article Twelve or the Corporation Code.

12.12 Notice. If the Corporation indemnifies or advances expenses to a director under any of the Sections of this Article Twelve or Sections 14-2-851 through 14-2-854 of the Nevada Corporation Code (or any equivalent provision of these by-laws) in connection with a proceeding by or in the right of the Corporation, the Corporation shall, to the extent required by Section 14-2-1621 or any other applicable provision of the Nevada Corporation Code, report the indemnification or advance of the Corporation's Annual Report to its shareholders or its 10K Report to the SEC.

12.13 Security. The Corporation may designate certain of its assets as collateral, provide self-insurance, establish one or more indemnification trusts, or otherwise secure or facilitate its ability to meet its obligations under this Article Twelve, or under any indemnification agreement or plan of indemnification adopted and entered into in accordance with the provisions of this Article Twelve, as the Board of Directors deems appropriate.

12.14 Amendment. Any amendment to this Article Twelve that limits or otherwise adversely affects the right of indemnification, advancement of expenses, or other rights of any Indemnified Person hereunder shall, as to such Indemnified Person, apply only to Proceedings based on actions, events, or omissions occurring after such amendment and after delivery of notice of such amendment to the Indemnified Person so affected in accordance with Section 13.5 (collectively, "Post Amendment Events"). Any Indemnified Person shall, as to any proceeding based on actions, events, or omissions occurring prior to the date of receipt of such notice, be entitled to the right of indemnification, advancement of expenses, and other rights under this Article Twelve to the same extent as if such provisions had continued as part of the by-laws of the Corporation without such amendment. This Paragraph 12.14 cannot be altered, amended, or repealed in a manner effective as to any Indemnified Person (except as to Post Amendment Events) without the prior written consent of such Indemnified Person.

12.15 Agreements. The provisions of this Article Twelve shall be deemed to constitute an agreement between the Corporation and each Indemnified Person hereunder. In addition to the rights provided in this Article Twelve, the Corporation shall have the power, upon authorization by the Board of Directors, to enter into an agreement or agreements providing to any Indemnified Person indemnification rights substantially similar to those provided for in this Article Twelve.

12.16 Continuing Benefits. The rights of indemnification and advancement of expenses permitted or authorized by this Article Twelve shall, unless otherwise provided when such rights are granted or conferred, continue as to a person who has ceased to be a director, officer, employee, or agent and shall inure to the benefit of the heirs, executors, and administrators of such person.

12.17 Successors. Any domestic or foreign entity that is the successor to all or substantially all of the business or assets of this Corporation, as a result of merger, consolidation, sale, liquidation, or otherwise, shall be liable to any Indemnified Person on the same terms and conditions and to the same extent as the Corporation.

12.18 Severability. Each of the Paragraphs of this Article Twelve, and each of the clauses set forth herein, shall be deemed separate and independent, and should any part of any such Paragraph or clause be declared invalid or unenforceable by any court of competent jurisdiction, such invalidity or unenforceability shall in no way render invalid or unenforceable any other part thereof or any separate Paragraph or clause of this Article Twelve that is not declared invalid or unenforceable.

12.19 Additional Indemnification. In addition to the specific indemnification rights set forth herein, the Corporation shall indemnify each of its directors and officers to the full extent permitted by action of the Board of Directors and the shareholders under the Nevada Corporation Code or other laws of the State of California as may be in effect from time to time.

**ARTICLE XIII  
AMENDMENTS**

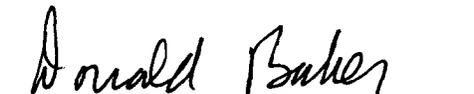
The by-laws of the Corporation may be altered or amended and new by-laws may be adopted by the shareholders at any annual or special meeting of the shareholders or by the Board of Directors at any regular or special meeting of the Board of Directors; provided, however, that if such action is to be taken at a meeting of the shareholders or meeting of the Board of Directors, written notice of the general nature of the proposed change in the by-laws shall be given in the notice of meeting. The shareholders may provide by resolution that any bylaw provision repealed, amended, adopted, or altered by them may not be repealed amended, adopted or altered by the Board of Directors. Action by the shareholders with respect to by-laws shall be taken by an affirmative vote of a majority of all shares entitled to elect directors, and action by the Board of Directors with respect to by-laws shall be taken by an affirmative vote of a majority of all directors then holding office.

WHEREAS, the Board of Directors has given its consent, the foregoing by-laws are adopted as the by-laws of GASTRODYNE, INC. as of the date set forth below.

WITNESS the due execution hereof as of this 2nd day of September, 2014.

  
\_\_\_\_\_  
Marvin P. Loeb

  
\_\_\_\_\_  
Glenn D. Yeik

  
\_\_\_\_\_  
Donald Baker

**GASTRODYNE, INC.**  
**Form 1-A Offering Statement**

**EXHIBIT 2.4**

**SUBSCRIPTION AGREEMENT**

GASTRODYNE, INC.

NAME: \_\_\_\_\_ NO. SHARES: \_\_\_\_\_ DATE: \_\_\_\_\_

GASTRODYNE, INC.

SUBSCRIPTION AGREEMENT  
AND LETTER OF INVESTMENT INTENT

IMPORTANT: PLEASE READ CAREFULLY AND COMPLETE FULLY BEFORE SIGNING;  
AS SIGNIFICANT REPRESENTATIONS ARE REQUIRED HEREIN.

Gastrodyne, Inc.  
5 Holland, Bldg. 223  
Irvine, CA 92618

Dear Sir:

1. The Undersigned Subscriber understands Gastrodyne, Inc. (the "Company", "we", "our" or "us") is offering up to 5 million shares of its \$0.001 par value Common Stock (the "Shares") at a price of \$1.00 per Share as described in the Offering Circular, Part II of the Form 1-A Offering Statement pursuant to Regulation A filed with the Securities and Exchange Commission (the "Commission") on \_\_\_\_\_, 2014, which will become qualified for sale on \_\_\_\_\_, 2014. No Shares will be sold to Non-Accredited Investors.

The Undersigned desires to become a stockholder of the Company and, on this \_\_\_\_ day of \_\_\_\_\_, 2014, hereby subscribes, upon the terms and conditions set forth below, for the purchase of \_\_\_\_\_ Shares of the Company at a price of \$1.00 per Share for an aggregate purchase price of \$\_\_\_\_\_. The Minimum Subscription in this Offering is 25,000 Shares for \$25,000, unless otherwise determined by the Company.

A check payable to "Gastrodyne, Inc." in full payment of the purchase price for the Shares is attached to this Subscription Agreement. The Undersigned acknowledges this Subscription is contingent upon acceptance in whole or part by the Company in its sole discretion. As used herein, the term "he" means he, she or it.

**PLEASE MAKE YOUR CHECK PAYABLE TO GASTRODYNE, INC. AND MAIL IT WITH THE SUBSCRIPTION AGREEMENT TO GASTRODYNE, INC. AT THE ADDRESS SHOWN ABOVE.**

This Offering is being made on a "Best Efforts" basis, and there is no assurance any or all of the Shares being offered will be sold. The proceeds from the sale of Shares in this Offering will be, to the extent this Subscription Agreement is accepted by the Company, immediately available for use the Company.

2. To the extent a Subscription Agreement is accepted by the Company, the Subscriber will be mailed a stock certificate for the number of Shares accepted by the Company within fifteen (15) days of its acceptance. The subscriber will receive a check refunding any part of the Subscription not accepted by the Company, but without interest thereon, within said fifteen (15) day period.
3. To the extent the Undersigned Subscriber's Subscription for Shares is accepted by the Company, the Undersigned Subscriber shall be issued one (1) Shareholder Warrant for each Share of this Subscription Agreement which is accepted by the Company. The terms and conditions of the

Shareholder Warrants are described in the Offering Circular (See "THE OFFERING AND PLAN OF DISTRIBUTION").

4. The Undersigned acknowledges and represents as follows:

(a) That he has accessed information on the Company, its products and plans in its Offering Circular, and that he has received and carefully reviewed the Company's Offering Circular and the Risk Factors contained therein.

(b) That he is able to bear the economic risk of an investment in the Shares of the Company and is a bona fide resident of or domiciled in the State of \_\_\_\_\_.

(c) That he has, or together with his investor representative has, such knowledge and experience in financial and business matters that he is capable of evaluating the merits and risks of his prospective investment in the Shares and that he is able to bear such risks. If the undersigned has designated an "investor representative" within the meaning of the Securities Act of 1933, as amended, to advise him with respect to an investment in the Shares, such investor representative is:

\_\_\_\_\_ (Telephone: \_\_\_\_\_).

(d) That he understands an investment in the Shares is highly speculative but believes that the investment is suitable for him based upon his investment objectives and financial needs, and he has adequate means for providing for his current financial needs and personal contingencies and has no need for liquidity of the Shares.

(e) That he has been given access to full and complete information regarding the Company in the Offering Circular, and that he has utilized such access to his satisfaction for the purpose of obtaining information in addition to, or verifying information included in, the Offering Circular.

(f) The Undersigned understands and agrees that forward looking statements, within the meaning of Section 27A of the U.S. Securities Act of 1993 and Section 21E of the Securities and Exchange Act of 1934, in the Offering Circular cannot be assured by the Company, and the Company's actual results and future events may differ materially from those described in the Offering Circular.

(g) That he is (check only one box) a  natural person,  sole proprietorship,  LLC,  partnership,  trust,  corporation; or  \_\_\_\_\_.

5. The Undersigned represents and warrants that the Shares are being purchased for his own account and that he has made no arrangement or agreement with others regarding any holding, resale, assignment or other disposition of the Shares.

6. The Undersigned represents and warrants that he is a bona fide resident of and is domiciled in the State set forth above in Paragraph 4(b) above and that the Shares are being purchased solely for the beneficial interest of the Undersigned and not as nominee for, or on behalf of, or for the beneficial interest of, or with the intention of their transfer to, any other person, entity or organization.

7. The Undersigned hereby approves the Company's 2014 Incentive and Non-Qualified Stock Option Plan (the "Option Plan") and the reservation of 2,000,000 Shares of the Company for the granting of options under the Option Plan and the reservation of 2,000,000 Shares for sale under the Company's Incentive Stock Purchase Plan and hereby waives the need for audited Financial Statements in the Offering Circular of the Company.

8. The Undersigned represents and warrants that the answers to the following questions are correct and he is: (check only one box and supply all requested information):

- A non-accredited person or entity.
- An accredited entity or person and the total purchase price for the Shares does not exceed 20% of the Undersigned's and his/her spouse's present net worth.
- A bank as defined in section 3(a) (2) of the Act whether acting in its individual or fiduciary capacity.
- An insurance company as defined in section 2(13) of the Act.
- An investment company registered under the Investment Company Act of 1940 or a business development company as defined in section 2(a) (48) of that Act.
- A Small Business Investment Company licensed by the U.S. Small Business Administration under section 301(c) or (d) of the Small Business Investment Act of 1958.
- An employee benefit plan within the meaning of Title I of the Employee Retirement Income Security Act of 1974, if the investment decision is made by a plan fiduciary, as defined in section 3(21) of such Act, which is either a bank, insurance company, or registered investment adviser, or if the employee benefit plan has total assets in excess of \$5,000,000.
- A private business development company as defined in section 202(a)(22) of the Investment Advisers Act of 1940.
- An organization described in section 501(c)(3) of the Internal Revenue Code with total assets in excess of \$5,000,000.
- A director or executive officer of the Company.
- An entity in which all of the equity owners are accredited investors under paragraph (a)(1), (2), (3), (4), (6), or (7) of Rule 501 of Regulation D promulgated under the Act. (Each equity owner must submit a signed statement verifying that he is an accredited investor.)

The Undersigned hereby represents that: (check one box)

(i) His yearly income (excluding his spouse's income) from all sources for each of 2012 and 2013 was in excess of (check highest number applicable):

<u>2012</u>	<u>2013</u>
<input type="checkbox"/> \$ 50,000	<input type="checkbox"/> \$ 50,000
<input type="checkbox"/> \$100,000	<input type="checkbox"/> \$100,000
<input type="checkbox"/> \$250,000	<input type="checkbox"/> Over \$250,000
<input type="checkbox"/> Over \$500,000	<input type="checkbox"/> Over \$500,000

(ii) He reasonably expects his yearly income (excluding his spouse's income) from all sources in 2014 to be in excess of (check highest number applicable):

\$50,000     \$100,000     \$250,000     \$500,000

(iii) His individual net worth, or his joint net worth with his spouse, at fair market value (including home, furnishings and personal automobiles) as of the date hereof is (check correct alternative):

Less than \$100,000     \$500,000 to \$750,000  
 \$100,000 to \$250,000     \$750,000 to \$1,000,000  
 \$250,000 to \$500,000     Over \$1,000,000

(iv) The portion of his net worth as shown above which is in liquid assets (cash, marketable securities or assets readily convertible to cash) as of the date hereof is (check correct alternative):

Less than \$50,000     \$50,000 to \$100,000  
 \$100,000 to \$250,000     \$250,000 to \$500,000  
 \$500,000 to 1,000,000     Over \$1,000,000

All of the foregoing information which the Undersigned has provided concerning the Undersigned, the Undersigned's financial position and the Undersigned's knowledge of financial and business matters, or, in the case of a corporation, partnership, trust, sole proprietorship or other entity, concerning the knowledge of financial and business matters of the person making the investment decision on behalf of such entity, is correct and complete as of the date set forth at the end hereof, and, if there should be any adverse change in such information prior to the Undersigned's subscription's being accepted, the Undersigned will immediately provide the Company with such information.

9. The Undersigned is aware of the significance to the Company of the foregoing representations, and they are made with the intention that the Company will rely upon them.

10. Type of Ownership desired (check only one box):

Individual Ownership

Joint Tenants with Rights of Survivorship (both parties must sign)

Trust or Estate (describe and enclose evidence of authority)

Corporation (describe and enclose evidence of authority)

Partnership (describe and enclose evidence of authority)

Other (describe below):  
\_\_\_\_\_  
\_\_\_\_\_

**WITNESS** the due execution hereof as of this \_\_\_\_\_ day of \_\_\_\_\_, 2014.

\_\_\_\_\_  
Name, Typed or Printed

\_\_\_\_\_  
Name, Typed or Printed, of Joint Owner, if any.

\_\_\_\_\_  
Business Address, if applicable.

\_\_\_\_\_  
Business Address, if applicable.

\_\_\_\_\_  
City, State and Zip Code

\_\_\_\_\_  
City, State and Zip Code

\_\_\_\_\_  
Residence Address, if applicable.

\_\_\_\_\_  
Residence Address, if applicable.

\_\_\_\_\_  
City, State and Zip Code

\_\_\_\_\_  
City, State and Zip Code

\_\_\_\_\_  
Tax Identification or Social Security Number

\_\_\_\_\_  
Tax Identification or Social Security Number

Office Phone ( ) \_\_\_\_\_

Office Phone ( ) \_\_\_\_\_

Home Phone ( ) \_\_\_\_\_

Home Phone ( ) \_\_\_\_\_

Email \_\_\_\_\_

Email \_\_\_\_\_

**SIGNATURES:**

\_\_\_\_\_  
Name of Company, if any, Typed or Printed.

\_\_\_\_\_  
Name of Company, if any, Types or Printed.

**Signed:** \_\_\_\_\_

**Signed:** \_\_\_\_\_

Print Name: \_\_\_\_\_

Print Name: \_\_\_\_\_

Title, if any: \_\_\_\_\_

Title, if any: \_\_\_\_\_

Date: \_\_\_\_\_, 2014

Date: \_\_\_\_\_, 2014

**ACCEPTANCE:**

This Subscription by the above named Subscriber for \_\_\_\_\_ Shares of the Company in this Offering is hereby accepted as of \_\_\_\_\_, 2014 to the extent of \_\_\_\_\_ Shares.

GASTRODYNE, INC.

By: \_\_\_\_\_

Print

Name: \_\_\_\_\_

Title:  Chairman,  President,  Treasurer

**GASTRODYNE, INC.**  
**Form 1-A Offering Statement**

**EXHIBIT 11**

**OPINION OF COUNSEL**

# OSTERGAR LAW GROUP P.C.

27101 Puerta Real, Suite 450 • Mission Viejo • California • 92691  
Telephone 949.305.4590 • Fax 949.305.4591

September 12, 2014

U.S. Securities and Exchange Commission  
100 F Street, NE  
Washington, D.C. 20549

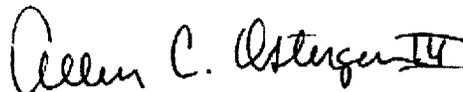
Re: Offering of Gastrodyne, Inc.

To Whom It May Concern:

As counsel for Gastrodyne, Inc., we have been requested to deliver to you our opinion of good standing and authority of Gastrodyne, Inc. It is our opinion that Gastrodyne, Inc. is in good standing in the State of Nevada with due authority to conduct its business. It is further our opinion that the Shares offered under this Offering Circular have been duly and validly authorized and the Shares will be, when issued, pursuant to Nevada law, fully paid and non-assessable.

Very truly yours,

OSTERGAR LAW GROUP P.C.



Allen C. Ostergar III

**GASTRODYNE, INC.**  
**Form 1-A Offering Statement**

**EXHIBIT 14**

**TWENTY YEAR RENEWBLE, EXCLUSIVE, WORLDWIDE  
PRIVATE LABEL AND DISTRIBUTION AGREEMENT**

TWENTY YEAR, RENEWABLE, EXCLUSIVE, WORLDWIDE  
PRIVATE LABEL AND DISTRIBUTION AGREEMENT

THIS TWENTY-YEAR, RENEWABLE, EXCLUSIVE, WORLDWIDE PRIVATE LABEL AND DISTRIBUTION AGREEMENT (the "Agreement"), dated as of September 3, 2014 (the "Effective Date"), is by and between TRIMEDYNE, INC. ("Trimedyne"), a Nevada corporation with its principal office at 5 Holland, Bldg. 223, Irvine, CA 92618, and GASTRODYNE, INC. ("the Company"), a Nevada corporation with its principal office at 5 Holland, Bldg. 223, Suite A, Irvine, CA 92618.

WHEREAS, Trimedyne manufactures proprietary Holmium Lasers ("Lasers") and patented and patent pending Side Firing Fibers ("Fibers") uniquely suited to (a) denervating malfunctioning nerves in the wall of the duodenum or in the outer layer or on the exterior of the celiac artery as it exits the duodenum to treat Type II Diabetes, (b) shrinking a loose pyloric valve of the lower stomach to prevent the continuous escape of partially digested food to treat Obesity and (c) shrinking the sphincter of a loose esophageal valve to prevent stomach acids from entering the esophagus and eroding its sensitive lining to treat Gastro Esophageal Reflux Disease or "GERD" (the "Conditions");

WHEREAS, Trimedyne does not have the funds necessary to conduct (a) at least four (4), 10 patient "pilot" clinical trials to demonstrate safety and Proof of Concept in the treatment of Type II Diabetes, Obesity or GERD and (b) up to four (4), 100 or more patient, randomized, controlled clinical trials to demonstrate safety and efficacy of the Lasers and Fibers in the treatment of Type II Diabetes (2 clinical trials), Obesity or GERD (1 clinical

trial of each) for FDA 510(k) clearances or PMAs and Medicare and other third-party reimbursement;

WHEREAS, the Company believes it has the ability to raise \$2.5 million or more within one (1) year from the Effective Date of this Agreement to (a) employ expert Gastroenterologists to write the Protocols for the 10 patient "Pilot clinical trials" and the 100 or more patient, randomized, controlled clinical trials and designate and train other gastroenterologists and their staffs to conduct such clinical trials, employ sales personnel to distribute Trimedyn's Lasers and Fibers worldwide, under the Company's name, logo and trademarks, if its clinical trials are successful, and obtain FDA 510(k) clearances or PMAs and Medicare and other third-party reimbursement for the use of the Lasers and Fibers provided by Trimedyn to the Company for the treatment of the Conditions;

WHEREAS, Trimedyn is willing to (a) manufacture its Lasers and Fibers and improved versions thereof for the Company at Trimedyn's GAAP Cost plus 35% and (b) to grant the Company, subject to the Company's raising at least \$2.5 million within a period of one (1) year from the Effective Date of this Agreement to finance the above clinical trials, and obtaining FDA clearances or PMAs and Medicare reimbursement for the treatment of those Conditions which merit these approvals (the "Approved Conditions"), the Exclusive, Worldwide Right to Distribute Trimedyn's Lasers and Fibers for the treatment of the Approved Conditions; and

WHEREAS, Trimedyn and the Company each wish to jointly enter into this Agreement to make this business arrangement mutually beneficial.

NOW THEREFORE, the parties hereto hereby agree as follows:

1. The Preambles to this Agreement are hereby incorporated herein by reference.

2. Trimedyne hereby agrees to sell its Lasers and Fibers, and improved versions thereof (the "Improved Versions"), to the Company, FOB Irvine, CA, or at such other location as it may hereafter from time to time designate in writing to the Company, at its GAAP Cost plus 35%, which Cost includes a one-year warranty on the Fibers and a one-year warranty on the Lasers, covering parts, labor and preventative maintenance. Trimedyne also agrees to provide, at its GAAP Cost plus 35%, extended warranty contracts to the Company for the Lasers the Company loans to customers who agree to purchase a specified number of Fibers per month from the Company.

3. The Company hereby agrees to purchase exclusively from Trimedyne, throughout the term of this Agreement, at Trimedyne's GAAP Cost plus 35%, (a) all of its requirements for Lasers and Fibers under the Company's name and label, except those to be used in its clinical trials, which shall be under Trimedyne's name and label, for the treatment of the Conditions, (b) all of its requirements for such Improved Versions of the Lasers and Fibers as the Company may from time to time hereafter request Trimedyne in writing to sell to it and (c) all of its requirements for Extended Service Contracts for such Lasers the Company loans to customers who agree to purchase a specified number of Fibers per month from the Company. Said GAAP Cost plus 35% shall include a one-

year warranty on the Fibers and a one year warranty on the Lasers, covering parts, labor and preventative maintenance.

4. If Trimedyne wishes to offer the Company the right to purchase Improved Versions of the Lasers and Fibers, Trimedyne will provide to the Company detailed written information on their construction, features, benefits, the one-time estimated cost of development and its estimated GAAP Cost plus 35%. If this offer is accepted in writing by the Company, the Company hereby agrees to pay the one-time development costs of such Improved Versions of the Lasers or Fibers as the Company may hereafter agree to purchase from Trimedyne at its GAAP Cost plus 35%, provided (a) Trimedyne and the Company agree in writing on the one-time development cost of such Improved Versions and (b) if Trimedyne agrees in the future to manufacture such Improved Versions of the Lasers or Fibers for third-parties, Trimedyne agrees, from time to time, to reapportion the one time development cost of such Improved Versions of the Lasers or Fibers between said third parties and the Company, and Trimedyne agrees to cause each of such third-parties to share the one-time development costs of such Improved Versions of the Lasers or Fibers on a pro-rata basis with the Company and reimburse the Company for their proportionate share of any one time development costs of such Improved Versions of the Lasers or Fibers paid-for by the Company.

5. In consideration of the Company's raising at least \$2.5 million within a period of one year from the Effective Date hereof, which the Company hereby agrees to use to conduct the above described clinical trials in the treatment of the Conditions and pay its management and overhead costs associated therewith, provided the clinical trial

of at least one or more of the Conditions is successful and FDA clearance or approval and Medicare coverage for such Conditions is obtained (the "Approved Conditions"), Trimedyne hereby grants the Company the exclusive right, throughout the term of this Agreement, to exclusively distribute throughout the world its Lasers and Fibers and such Improved Versions thereof, as the Company may require, for the treatment of the Approved Conditions. Trimedyne also hereby agrees, during the Term of this Agreement, not to compete with the Company in the treatment of the Approved Conditions and to not supply or grant licenses to make, use or sell Lasers and Fibers and Improved Versions thereof which are able to substantially perform the same function as those it supplies to the Company to any third-parties for use in the treatment of the Approved Conditions.

6. Trimedyne owns a number of U.S. Patents and U.S. Patent Applications covering its Fibers and Improved Versions thereof. Trimedyne shall maintain its existing U.S. Patents at its expense and shall prosecute its existing U.S. Patent Applications and those Patent Applications it may hereafter file in the U.S. covering its Lasers or Fibers and Improved Versions thereof at its expense. If any of the above U.S. Patent Applications issue as U.S. Patents, Trimedyne shall also maintain them at its expense.

7. However, if the Company wishes to file and prosecute any counterparts or divisions of any of such U.S. Patent Applications in countries of its choice outside the United States covering the Conditions, the Company hereby agrees to pay the cost of filing and prosecution of such counterparts or divisions of U.S. Patent Applications and the cost of issuance and maintenance fees of any foreign Patents that issue from such counterparts or divisions, including legal fees, filing fees and translation costs. All foreign Patent Applications and any foreign Patents that issued therefrom shall be filed in

Trimedyne's name and assigned to Trimedyne, and Trimedyne hereby agrees the Company shall have the benefit of the protection afforded by them, throughout the term of this Agreement, free of royalty thereon.

8. In the event a third party that owns or holds a U.S. or foreign Patent or a license to a U.S. or foreign Patent files a claim alleging infringement of its Patent by the use of any of Trimedyne's Lasers or Fibers, or Improved Versions thereof in the treatment of any of the Approved Conditions, the Company and Trimedyne hereby agree to jointly defend against such claim, sharing the legal fees and costs of defense on a 50%/50% basis.

9. In the event Trimedyne or the Company learns of a laser or side firing fiber or any focused thermal energy source of a third party being used to treat any of the Approved Conditions, which Trimedyne or the Company believes may infringe a U.S. or foreign Patent owned by Trimedyne, they shall so advise the other. Trimedyne and the Company may jointly take legal action to prevent such infringement, paying the legal fees and costs of the action in a 50%/50% basis. If either of them do not agree to do so, Trimedyne shall have the first right to take legal action to stop such infringement. If Trimedyne does so, Trimedyne shall, after recovering its legal fees and costs, retain 60% and the Company shall receive 40% of the remainder of all damages, settlements, license fees and royalties. If Trimedyne chooses not to do so, Trimedyne shall so promptly advise the Company in writing, and the Company shall have the option to take legal action to stop such infringement and, if it does so, after recovering its legal fees and costs, the Company shall retain 60% and Trimedyne shall receive 40% of the remainder of all damages, settlements, license fees and royalties. If the Company does not wish to do

so, it will promptly give Trimedyne written notice of its decision to not oppose such infringement, in which case Trimedyne may elect to oppose such infringement, on the terms and conditions described above. Neither party hereto shall agree to the terms or conditions of a damage award, a settlement amount, a license fee or royalty, in court or privately, without the consent of the other party to this Agreement.

10. In consideration of Trimedyne's (a) selling its Lasers and Fibers improved versions thereof to the Company at its GAAP Cost plus 35%, versus its usual mark-up of 60% to 200%, for the treatment of any of the Conditions, (b) granting the Company the exclusive, worldwide right to distribute its Lasers and Fibers and Improved Versions thereof for the treatment of any of the Conditions and (c) allowing the Company to use the protections of its U.S. Patents and its FDA clearances, CE Marks and registrations in many countries outside the U.S. and the E.U. that require their own registration of medical devices for sale in their jurisdictions, the Company hereby agrees to privately sell Trimedyne three million (3,000,000) shares of its Common Stock (\$0.001 par value) at a price of \$0.01 per share, and Trimedyne hereby agrees to purchase and promptly pay for said 3,000,000 shares of the Company's common stock at such price.

11. Trimedyne's independent public accountants shall, within four (4) months after the end of each of Trimedyne's Fiscal years, give a written certification to the Company that Trimedyne has not charged the Company more than Trimedyne's GAAP Cost plus 35% for Lasers, Fibers and any Improved Versions thereof, during Trimedyne's immediately prior Fiscal year. The Company or its agents or accountants shall, from time to time, have the right to inspect the books and records of Trimedyne, upon five (5) days prior written notice to Trimedyne, during Trimedyne's customary business hours, to

confirm the accuracy of Trimedyne's GAAP Cost plus 35% charge over one or more of Trimedyne's past fiscal years. Any overstatement of such GAAP Cost plus 35% shall be paid by Trimedyne to the Company within ten (10) days of the Company's presentation to Trimedyne of evidence of such overstatement, along with a penalty fee of ten percent (10%) of the amount of any overcharge. Once a fiscal year has been so inspected, such fiscal year may not be re-inspected by the Company.

12. In the event either party hereto is delayed or prevented from fulfilling any of its respective obligations under this Agreement for any reason beyond its reasonable control, including Acts of God, fire, flood, strike, riot, war, insurrection, delay of transportation or inability to obtain necessary components or raw materials through normal commercial channels, herein referred to as "Force Majure", such party shall not be liable under this Agreement for any such delay or failure except as may be determined by final and binding arbitration, to which both parties hereto agree to submit, decided by one arbitrator under the Commercial Arbitration Rules of the American Arbitration Agreement in Orange County, California.

13. Periodic written quarterly forecasts of the Company's quarterly needs for Lasers, Fibers and Improved Versions thereof from Trimedyne shall be provided by the Company to Trimedyne, commencing one (1) year after the clinical results of the Company's 100 or more patient clinical trials are available and FDA clearance or approval to market the same and Medicare reimbursement for the same are obtained for at least one Approved Condition. If any of these forecasts are not revised or cancelled at least four months before their starting date, they shall become binding purchase orders.

14. The Company may, at its sole option, advance to Trimedyne all or part of such funds as Trimedyne believes is necessary to establish a field service organization to repair and maintain the Lasers purchased by the Company from Trimedyne in the countries in which the Company is commencing to market Trimedyne's Lasers, Fibers and Improved Versions thereof for the treatment of an Approved Condition. The terms of repayment of all funds advanced to Trimedyne by the Company, if any, will be set forth in a separate agreement, subject to its approval by the Boards of Directors of the Company and Trimedyne.

15. This Agreement shall commence on the Effective Date set forth above and shall continue for a term of twenty (20) years (the "Term"). This Agreement shall automatically renew for successive Terms of twenty (20) years each, unless this Agreement is not renewed by the Company or Trimedyne by written notice to the other party at least nine (9) months prior to the expiration date of the then Term of this Agreement. If the Company fails to raise at least \$2,500,000 within one (1) year from the Effective Date of this Agreement, this Agreement shall terminate, unless extended in writing by Trimedyne, or, if the Company fails to obtain FDA clearance or approval and Medicare reimbursement of one or more of the Conditions (the "Approved Conditions"), this Agreement shall terminate with respect to any of the Conditions which do not become Approved Conditions within six (6) years from the Effective date of this Agreement, unless extended in writing by Trimedyne.

16. In the event of a disagreement between the parties pertaining to the terms or conditions of this Agreement or a default or breach of this Agreement or any of its terms or conditions by a party hereto, the disagreeing, defaulting or breaching party shall have

a period of sixty (60) days, from the date of notice of such disagreement, default or breach by the other party, to cure the disagreement default or breach. If not so cured, both parties hereto agree to submit to final and binding arbitration of the disagreement, default or breach, by a single arbitrator, under the Commercial Arbitration Rules of the American Arbitration Association in Orange County, California.

17. No waiver of any disagreement, breach or default under this Agreement shall be effective as to any other disagreement, breach or default of this Agreement.

18. During the term of this Agreement, each of the parties hereto shall receive or learn of confidential and proprietary information (the "Information") of the other party hereto. Each party hereto agrees to maintain the confidentiality of such Information, not disclose it to any third party and shall protect the confidentiality of such Information, exercising the same level of care it takes to assure the confidentiality of its own confidential or proprietary information. In the event of a breach of this provision by either party hereto, in addition to other remedies, the breaching party hereby agrees the damaged party shall be entitled to injunctive relief, and both parties hereto agree to be bound by the binding arbitration provision set forth above in Paragraph 18 in resolving this situation.

19. All obligations required or intended to be performed by either or both of the parties hereto after the expiration or termination of this Agreement, shall survive the expiration or termination of this Agreement.

20. Neither party to this Agreement shall assign to a third party this Agreement or any of its rights or privileges under this Agreement without the express written consent

of the other party hereto, provided however, either party hereto may assign this Agreement and its rights and privileges thereunder, without the express written consent of the other party thereto, to any person or entity which acquires a majority of the equity securities or substantially all of the assets of a party hereto.

21. The parties hereto agree to negotiate from time to time additional terms and conditions of this Agreement common to Private Label Agreements, which shall be set forth from time to time in an Addendum hereto, duly executed by officers of both parties hereto and approved by their respective Boards of Directors. Such terms and conditions shall include, but are not limited to, the quality and specifications of the Lasers and Fibers and Improved Versions thereof provided by Trimedyne to the Company hereunder.

22. This Agreement represents the only agreement or understanding, oral or in writing, as of this date, between the parties hereto, and this Agreement shall not be amended, modified or changed except in a writing executed by duly authorized officers of both parties hereto and approved by their respective Boards of Directors.

23. This Agreement shall be construed under the laws of the State of California, regardless of conflicts of laws, and this Agreement shall inure to and be binding upon the respective successors and permitted assigns of the parties hereto.

24. If any provision of this Agreement is found to be unenforceable, such provision shall not affect the enforceability of any other provision hereof.

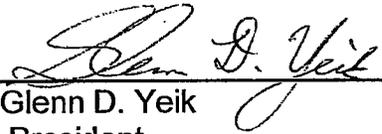
25. Both parties hereto participated in the negotiation of the terms and conditions and in the preparation of this Agreement.

26. Each party hereto shall notify the other party in writing within thirty (30) days of moving its headquarters to an address different from the address set forth above or listed in a prior notice. All notices required or permitted to be given under this Agreement shall be deemed effective and given when delivered in person, by Email or facsimile or sent by certified mail, postage prepaid, return receipt requested, to the party to be notified at its address set forth above or to any other address hereafter designated in writing by either party hereto.

IN WITNESS WHEREOF, the respective parties hereto have caused this Agreement to be executed by their respective duly authorized officers as of the date first above written.

TRIMEDYNE, INC.

GASTRODYNE, INC.

By:   
Glenn D. Yeik  
President

By:   
Marvin P. Loeb  
Chairman

Date: September 3, 2014

Date: September 3, 2014

**GASTRODYNE, INC.**  
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## News Release

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### Medtronic Signs Agreement to Acquire Ardian

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MINNEAPOLIS & MOUNTAIN VIEW, Calif., Nov 22, 2010 (BUSINESS WIRE) --

Medtronic, Inc. (NYSE: MDT) and privately-held Ardian, Inc. announced today that they have entered into a merger agreement whereby Medtronic will acquire Ardian. The agreement calls for Medtronic to make an up front cash payment of \$800 million, plus commercial milestones equal to the annual revenue growth through the end of Medtronic's fiscal year 2015. Medtronic had previously invested in Ardian and currently holds an 11 percent ownership stake in the Company.

Based in Mountain View, Calif., Ardian develops catheter-based therapies to treat hypertension and related conditions.

"Hypertension (high blood pressure) is the leading attributable cause of death worldwide. It is a significant, escalating global healthcare problem affecting approximately 1.2 billion people and is associated with an increased risk of heart attack, stroke, heart failure, kidney disease and death," said Sean Salmon, Vice President and General Manager of the Coronary and Peripheral Business at Medtronic. "We view renal denervation for the treatment of uncontrolled hypertension as one of the most exciting growth markets in medical devices. Ardian's investigational catheter-based treatment for uncontrolled hypertension through renal nerve denervation complements Medtronic's expertise in catheter design and ablation technologies, and augments Medtronic's interventional therapies."

Data from a clinical study of Ardian's flagship product, the Symplicity<sup>(R)</sup> Catheter System (TM), were recently released at the American Heart Association 2010 Scientific Sessions in Chicago and published in *The Lancet*. It was reported that patients treated with the Ardian device experienced a 33 mmHg greater reduction in systolic blood pressure at six months (p<0.0001) than the control group. The Symplicity Catheter System has received CE mark and Australia TGA listing, but is not approved for sale in the U.S.

"Ardian brings to Medtronic the Symplicity Catheter System and a growing body of evidence to support its clinical use for patients whose hypertension remains uncontrolled despite optimal medical management," said Andrew Cleeland, President and CEO of Ardian. "Our integration into Medtronic creates a tremendous opportunity to leverage Medtronic's global scale and scope to advance the treatment of uncontrolled hypertension."

111-52

The transaction is expected to close in Medtronic's third fiscal quarter of 2011, and is subject to customary closing conditions, including U.S. and foreign regulatory clearances.

## ABOUT ARDIAN

Privately held Ardian, Inc., based in Mountain View, Calif., develops catheter-based therapies to treat hypertension and related conditions. Ardian is the eighth company created by The Foundry, a leading medical device incubator based in Menlo Park, Calif. Ardian's investors include Morgenthaler Ventures, Advanced Technology Ventures, Split Rock Partners, Medtronic and Emergent Medical Partners. For more information, please visit [www.ardian.com](http://www.ardian.com).

## ABOUT MEDTRONIC

Medtronic, Inc. ([www.medtronic.com](http://www.medtronic.com)), headquartered in Minneapolis, is the global leader in medical technology - alleviating pain, restoring health and extending life for millions of people around the world.

***This Press Release contains forward-looking statements that may include statements regarding the intent, belief or current expectations of Ardian, Medtronic and their respective management. Forward-looking statements include statements about the benefits and advantages of the acquisition for Ardian, and the benefits of the acquisition for Medtronic post-transaction, such as product development opportunities and operating synergies. Actual results could differ materially from those projected in the forward-looking statements as a result of a number of important factors, including but not limited to the risk that the acquisition of Ardian by Medtronic will not close as the transaction is subject to certain closing conditions, such as the ability to obtain U.S. and foreign regulatory approvals of the proposed acquisition, including antitrust approval, and the approval of the transaction by Ardian's stockholders. In addition, if and when the transaction is closed, there will be risks and uncertainties related to Medtronic's ability to integrate Ardian successfully, the risk that the cost savings and any other synergies from the acquisition may not be fully realized or may take longer to realize than expected; disruption from the acquisition making it more difficult to maintain relationships with customers, employees or suppliers; and competition and its effect on pricing, spending, third-party relationships and revenues. Additional factors that may affect future results are contained in the SEC filings for Medtronic, including but not limited to Medtronic's Annual Report on Form 10-K for the year ended April 30, 2010. Medtronic and Ardian each disclaim any obligation to update and revise statements contained in this release based on new information or otherwise.***

Photos/Multimedia Gallery Available: <http://www.businesswire.com/cgi-bin/mmg.cgi?eid=6521665&lang=en>

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111-53



# Renal sympathetic denervation in patients with treatment-resistant hypertension (The Symplicity HTN-2 Trial): a randomised controlled trial



Symplicity HTN-2 Investigators\*

## Summary

Background Activation of renal sympathetic nerves is key to pathogenesis of essential hypertension. We aimed to assess effectiveness and safety of catheter-based renal denervation for reduction of blood pressure in patients with treatment-resistant hypertension.

**Methods** In this multicentre, prospective, randomised trial, patients who had a baseline systolic blood pressure of 160 mm Hg or more ( $\geq 150$  mm Hg for patients with type 2 diabetes), despite taking three or more antihypertensive drugs, were randomly allocated in a one-to-one ratio to undergo renal denervation with previous treatment or to maintain previous treatment alone (control group) at 24 participating centres. Randomisation was done with sealed envelopes. Data analysers were not masked to treatment assignment. The primary effectiveness endpoint was change in seated office-based measurement of systolic blood pressure at 6 months. Primary analysis included all patients remaining in follow-up at 6 months. This trial is registered with ClinicalTrials.gov, number NCT00888433.

**Findings** 106 (56%) of 190 patients screened for eligibility were randomly allocated to renal denervation ( $n=52$ ) or control ( $n=54$ ) groups between June 9, 2009, and Jan 15, 2010. 49 (94%) of 52 patients who underwent renal denervation and 51 (94%) of 54 controls were assessed for the primary endpoint at 6 months. Office-based blood pressure measurements in the renal denervation group reduced by 32/12 mm Hg (SD 23/11, baseline of 178/96 mm Hg,  $p<0.0001$ ), whereas they did not differ from baseline in the control group (change of 1/0 mm Hg [21/10], baseline of 178/97 mm Hg,  $p=0.77$  systolic and  $p=0.83$  diastolic). Between-group differences in blood pressure at 6 months were 33/11 mm Hg ( $p<0.0001$ ). At 6 months, 41 (84%) of 49 patients who underwent renal denervation had a reduction in systolic blood pressure of 10 mm Hg or more, compared with 18 (35%) of 51 controls ( $p<0.0001$ ). We noted no serious procedure-related or device-related complications and occurrence of adverse events did not differ between groups; one patient who had renal denervation had possible progression of an underlying atherosclerotic lesion, but required no treatment.

**Interpretation** Catheter-based renal denervation can safely be used to substantially reduce blood pressure in treatment-resistant hypertensive patients.

**Funding** Ardian.

## Introduction

Successful treatment of raised blood pressure has proven elusive despite availability of various drugs, combination pharmaceutical products, and resources to assist patients' adherence and lifestyle changes. In about half of hypertensive patients, blood pressure remains higher than accepted treatment targets despite broad availability of effective pharmaceutical agents.<sup>1,2</sup> The failure of present strategies suggests underlying pathophysiology that is refractory to available pharmacological interventions, inherent limitations of present pharmacological strategy, physician inertia, or antipathy of patients to lifelong multidrug treatment for a predominantly asymptomatic disease.

Renal sympathetic nerves contribute to development and perpetuation of hypertension, and sympathetic outflow to the kidneys is activated in patients with essential hypertension.<sup>3</sup> Efferent sympathetic outflow

stimulates renin release, increases tubular sodium reabsorption, and reduces renal blood flow.<sup>4</sup> Afferent signals from the kidney modulate central sympathetic outflow and thereby directly contribute to neurogenic hypertension.<sup>5,7</sup>

Non-selective surgical sympathectomy was effectively used as a treatment of severe hypertension before antihypertensive drugs became generally available.<sup>8,9</sup> Recently developed endovascular catheter technology enables selective denervation of the human kidney, with radiofrequency energy delivered in the renal artery lumen, accessing the renal nerves located in the adventitia of the renal arteries. A first-in-man study of this approach<sup>10</sup> showed successful renal denervation with reduction of sympathetic activity and renin release in parallel with reductions of central sympathetic outflow. Safety and feasibility trials of this procedure identified substantial reductions of blood pressure without substantial

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See Comment page 1878

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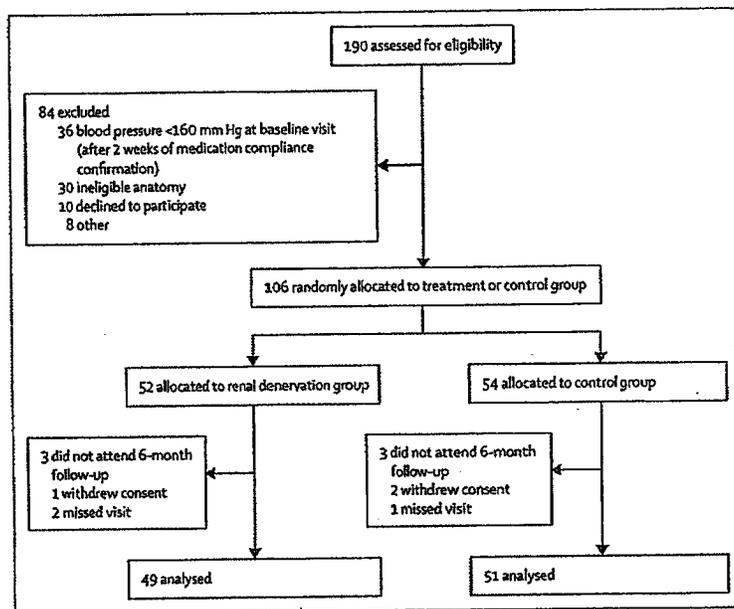


Figure 1: Trial profile

procedure-related complications.<sup>11</sup> We report results from a randomised trial that aimed to show that catheter-based renal denervation could safely reduce blood pressure in patients with treatment-resistant hypertension.

## Methods

### Study design and patients

Symplicity HTN-2 was an international, multicentre, randomised study of the safety and effectiveness of renal denervation in patients with treatment-resistant hypertension. Patients aged 18–85 years with a systolic blood pressure of 160 mm Hg or more ( $\geq 150$  mm Hg in patients with type 2 diabetes), despite compliance with three or more antihypertensive drugs, were eligible for inclusion. Exclusion criteria included an estimated glomerular filtration rate (eGFR; based on the Modification of Diet in Renal Disease criteria<sup>12</sup>) of less than 45 mL/min per 1.73 m<sup>2</sup>, type 1 diabetes, contraindications to MRI, substantial stenotic valvular heart disease, pregnancy or planned pregnancy during the study, and a history of myocardial infarction, unstable angina, or cerebrovascular accident in the previous 6 months. Full details of inclusion and exclusion criteria are detailed in the online protocol.

Screening was done at 24 centres in Europe, Australia, and New Zealand; 16 (67%) were hypertension centres of excellence as designated by the European Society of Hypertension or by one of the European national hypertension societies. As part of the screening process, patients were required to record twice daily automated home blood pressure measurements and to document drug compliance for 2 weeks. Patients whose blood pressure was below the enrolment criteria when they

returned to the clinic for blood-pressure measurement were excluded. Before randomisation, patients underwent renal artery anatomical screening with renal duplex, computed tomography, MRI, or renal angiography to confirm anatomical eligibility. Patients with haemodynamically significant renal artery stenosis, previous renal artery intervention, or renal artery anatomy that precluded treatment (defined as <4 mm diameter, <20 mm length, or more than one main renal arteries) were excluded. We recorded baseline serum creatinine, cystatin C, spot urine albumin-to-creatinine ratio, and 24-h ambulatory blood pressure before randomisation. The study was approved by the ethics committees at every participating site, and all patients provided written informed consent.

### Randomisation

Patients were randomly assigned to intervention group with sealed envelopes at every clinical site in a one-to-one ratio to undergo catheter-based renal denervation with the Symplicity Catheter System (Ardian, Mountain View, CA, USA) or to the control group. Data analysers were not masked to treatment-group assignment. Background use of antihypertensive drugs was constant in both groups.

### Procedures

For patients randomly assigned to undergo renal denervation, the femoral artery was accessed with the standard endovascular technique and the Symplicity catheter was advanced into the renal artery and connected to a radiofrequency generator. As previously described,<sup>11</sup> four-to-six discrete, low-power radiofrequency treatments were applied along the length of both main renal arteries. Participants were given heparin to achieve an activated clotting time of more than 250 s. Intraprocedural diffuse visceral pain that was restricted to the duration of energy delivery was managed with intravenous anxiolytics and narcotics.

For both renal denervation and control groups, changes to baseline doses of all anti-hypertensive drugs were not allowed, unless judged medically necessary because of changes in blood pressure in association with signs or symptoms. Specific agents added or withdrawn were selected at the discretion of the investigators.

Patients were followed up at 1, 3, and 6 months with assessment of adverse events and drugs, and measurements of office-based blood pressure, serum creatinine concentration, cystatin C concentration, and urine albumin-to-creatinine ratio. 2 weeks before the 6-month visit, patients completed daily automated home blood pressure monitoring and drug compliance diaries. At 6 months, we repeated ambulatory blood-pressure monitoring. We imaged the kidneys of patients in the renal denervation group at 6 months, mainly by renal duplex ultrasound and subsequently by CT angiogram or magnetic-resonance angiogram (if duplex imaging identified a clinically significant abnormality).

For the Symplicity HTN-2 protocol see <http://www.ardian.com/symplicityHTN2.pdf>

Office-based blood pressure measurements were taken with an automatic oscillometric Omron HEM-705 monitor (Omron Healthcare, Vernon Hills, IL, USA) with a printer for documentation. Blood pressure was measured according to protocol-specified guidelines based on Standard Joint National Committee VII, European Society of Cardiology, and European Society of Hypertension recommendations.<sup>13,14</sup> We used averages of triplicate measurements in our analysis.

For assessments of blood pressure at home, we provided patients with an automatic Omron HEM-705 monitor to record 2 weeks of daily seated blood pressure, three times in the morning and three times in the evening. We used averages of the home measurements at baseline and 6-month visits for analysis.

We measured 24-h ambulatory blood pressure with an oscillometric Spacelabs 90207 monitor (Spacelabs Healthcare, Issaquah, WA, USA) with readings taken every 15 mins in daytime and every 30 mins at night-time, and calculated overall 24-h averages for every patient. Only ambulatory blood-pressure assessments that met European Society of Cardiology and European Society of Hypertension guidelines (with more than 70% of daytime and night-time readings) were regarded as technically sufficient for inclusion in the analysis.<sup>14</sup>

### Endpoints

The primary effectiveness endpoint was between-group change in average office-based measurements of systolic blood pressure from baseline to 6 months after randomisation. Secondary endpoints were acute procedural safety, chronic procedural safety (reduction of eGFR >25% or new stenosis >60% confirmed by angiogram at 6 months), a composite cardiovascular endpoint (myocardial infarction, sudden cardiac death, new-onset heart failure, death from progressive heart failure, stroke, aortic or lower limb revascularisation procedure, lower limb amputation, death from aortic or peripheral arterial disease, dialysis, death because of renal failure, hospital admission for hypertensive emergency unrelated to non-adherence or non-persistence with drugs, and hospital admission for atrial fibrillation), and additional measurements of blood-pressure reduction at 6 months after randomisation consisting of occurrence of 10 mm Hg or more systolic response, achievement of target systolic blood pressure, change in 24-h ambulatory blood pressure, and change in home-based blood-pressure measurements. The principal investigator (MDE) reviewed all reported adverse events in parallel with an independent data and safety monitoring board.

### Statistical analysis

With a sample of 50 patients per group, we calculated that the study would have at least 80% power to show benefit of renal denervation over control intervention, with respect to the primary endpoint, assuming at least a 12 mm Hg difference between groups and a 21 mm Hg

standard deviation of the change in systolic blood pressure from baseline to 6 months. All analyses were done with data for all patients at randomisation minus those lost to follow-up. We assessed continuous variables between groups, including the primary endpoint, with Student's two-sample *t* test unless otherwise specified. We compared categorical variables with Fisher's exact test. For within-group paired data, a paired *t* test was used unless otherwise specified. A two-sided alpha level of 0.05 was used for all superiority testing. All statistical analyses were done with SAS version 9.2.

This trial is registered with ClinicalTrials.gov, number NCT00888433.

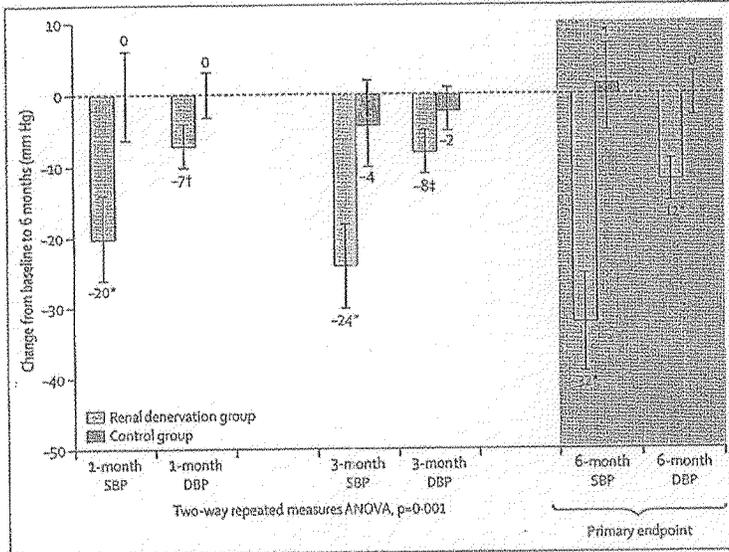
### Role of the funding source

The study was designed by MDE and advisers, including local investigators, and the sponsor (Ardian). Data were

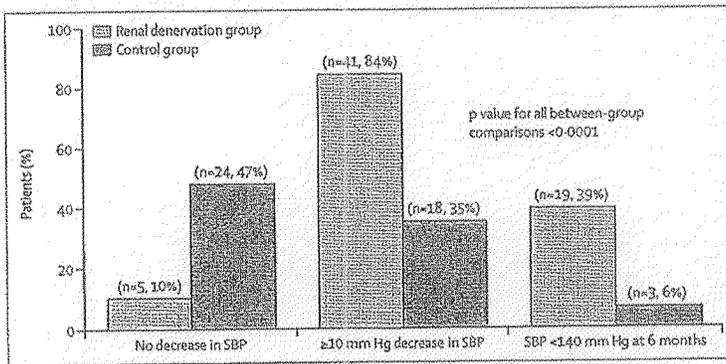
	Renal denervation group (n=52)	Control group (n=54)
Baseline systolic blood pressure (mm Hg)	178 (18)	178 (16)
Baseline diastolic blood pressure (mm Hg)	97 (16)	98 (17)
Age (years)	58 (12)	58 (12)
Sex (female)	18 (35%)	27 (50%)
Race (White)	51 (98%)	52 (96%)
Body-mass index (kg/m <sup>2</sup> )	31 (5)	31 (5)
Type 2 diabetes	21 (40%)	15 (28%)
Coronary artery disease	10 (19%)	4 (7%)
Hypercholesterolaemia	27 (52%)	28 (52%)
eGFR* (mL/min per 1.73 m <sup>2</sup> )	77 (19)	86 (20)
eGFR* 45–60 mL/min per 1.73 m <sup>2</sup>	11 (21%)	6 (11%)
Serum creatinine (μmol/L)	91 (25)	78 (18)
Urine albumin-to-creatinine ratio (mg/g)†	128 (363)	109 (264)
Cystatin C (mg/L)‡	0.9 (0.2)	0.8 (0.2)
Heart rate (bpm)	75 (15)	71 (15)
Number of antihypertension medications	5.2 (1.5)	5.3 (1.8)
Patients on hypertension medication for more than 5 years	37 (71%)	42 (78%)
Patients on five or more medications	35 (67%)	31 (57%)
Patients receiving (drug class)		
ACE inhibitors/ARBs	50 (96%)	51 (94%)
Direct renin inhibitors	8 (15%)	10 (19%)
β-blockers	43 (83%)	37 (69%)
Calcium channel blockers	41 (79%)	45 (83%)
Diuretics	45 (86%)	49 (91%)
Aldosterone antagonist	9 (17%)	9 (17%)
Vasodilators	8 (15%)	9 (17%)
α-1 blockers	17 (33%)	10 (19%)
Centrally acting sympatholytic	27 (52%)	28 (52%)

Data are mean (SD) or number (%). eGFR=estimated glomerular filtration rate; ACE=angiotensin-converting enzyme; ARB=angiotensin receptor blocker. \*Calculated on the basis of Modification of Diet in Renal Disease Study criteria. †42 participants in the renal denervation group and 43 participants in the control group used for between-group comparisons with the Wilcoxon rank-sum test for two independent samples. ‡39 participants in the renal denervation group and 42 participants in the control group had data for cystatin C available at baseline.

Table 1: Baseline clinical characteristics, demographics, and background medications for participants assigned to renal denervation or control groups



**Figure 2:** Paired changes in office-based measurements of systolic and diastolic blood pressures at 1 month, 3 months, and 6 months for renal denervation and control groups. Error bars are 95% CI. Multivariable stepwise regression analysis of baseline characteristics, drugs, and treatment assignment was examined for predictors of increased 6-month systolic-blood-pressure response; only variables with  $p < 0.15$  on univariate screening were entered into the model with variables with  $p < 0.05$  remaining in the final model. Multivariable analysis of baseline characteristics showed that assignment to the renal denervation group ( $p < 0.0001$ ), higher baseline systolic blood pressure ( $p < 0.0001$ ), and slower heart rate ( $p < 0.004$ ) predicted increased 6-month blood-pressure reduction. SBP=systolic blood pressure. DBP=diastolic blood pressure. \* $p < 0.0001$ . † $p = 0.002$ . ‡ $p = 0.005$ .



**Figure 3:** Proportion of patients in the renal denervation and control groups that at 6 months had no decrease in systolic blood pressure, a 10 mm Hg or greater decrease in SBP, or achieved a SBP of less than 140 mm Hg. SBP=systolic blood pressure.  $p$  value for all between-group comparisons  $< 0.0001$ .

monitored, collected, and managed by the sponsor. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

**Results**

From June 9, 2009, to Jan 15, 2010, 106 (56%) of 190 patients screened were eligible for study inclusion and were randomly allocated to renal denervation or control groups (figure 1). Patients in the two study groups did not differ

by age, sex, baseline systolic or diastolic blood pressure, race, most comorbidities, and reported duration spent on antihypertensive therapy (table 1). Patients in the renal denervation group had a lower baseline renal function than did the control group, as assessed by eGFR (77 mL/min per 1.73 m<sup>2</sup> vs 86 mL/min per 1.73 m<sup>2</sup>;  $p = 0.013$ ), but baseline cystatin C concentrations did not differ between groups. Patients in both groups were taking much the same numbers and types of antihypertensive drugs (table 1). Diuretics, including aldosterone antagonists, were used in more than 89% of patients.

Of 106 patients who were randomly allocated to intervention or control groups, we analysed the primary endpoint for 49 patients who underwent renal denervation and 51 controls. Three patients in each group were lost to follow-up because of withdrawal of consent or missed visits (figure 1). 6 months after randomisation, office-based measurements of blood pressure in the renal denervation group were reduced by 32/12 mm Hg (SD 23/11) from 178/96 mm Hg (18/16) at baseline ( $p < 0.0001$  for systolic and diastolic blood pressure). By contrast, office-based measurements of blood pressure in the control group changed by 1/0 mm Hg (SD 21/10) from 178/97 mm Hg (17/16) at baseline ( $p = 0.77$  for systolic blood pressure,  $p = 0.83$  for diastolic blood pressure; figure 2). Therefore, a 33/11 mm Hg reduction in blood pressure was noted in the renal denervation group compared with the control group ( $p < 0.0001$  for systolic and diastolic blood pressure) during 6-month follow-up.

We noted much the same changes in home-based blood pressure measurements. Blood pressure fell by 20/12 mm Hg (SD 17/11) in 32 patients in the renal denervation group, compared with a rise of 2/0 mm Hg (13/7) in 40 controls. The absolute difference between groups was 22/12 mm Hg ( $p < 0.0001$  for systolic and diastolic blood pressure).

Average blood pressure at 6 months derived from 24-h ambulatory blood-pressure monitoring changed in parallel with office-based and home-based systolic blood-pressure measurements. 24-h ambulatory blood-pressure recordings were available for 20 patients in the renal denervation group, showing a mean decrease of 11/7 mm Hg (SD 15/11;  $p = 0.006$  for systolic blood pressure change,  $p = 0.014$  for diastolic blood pressure change) from baseline to 6 months, whereas averages did not change for 25 patients in the control group (-3/-1 mm Hg [19/12];  $p = 0.51$  for systolic,  $p = 0.75$  for diastolic).

Figure 3 shows the proportions of patients achieving defined thresholds of systolic blood pressure reduction at 6 months. More patients who underwent renal denervation had reductions in systolic blood pressure than did controls, with reductions of 10 mm Hg or greater more common, as was achievement of a target of less than 140 mm Hg (all  $p < 0.0001$ ; figure 3).

Ten (20%) of 49 patients who underwent renal denervation had drug reductions prior to the 6-month follow-up, compared with three (6%) of 51 controls

	Renal denervation group		Control group		Difference in mean change (95% CI)	p value
	Patients (n)	Mean change (SD)	Patients (n)	Mean change (SD)		
eGFR* (ml/min per 1.73 m <sup>2</sup> )	49	0.2 (11)	51	0.9 (12)	0.7 (-5.4 to 3.9)	0.76
Serum creatinine (μmol/l)	49	0.2 (17.6)	51	1.1 (10.3)	1.3 (-4.5 to 7.0)	0.67
Cystatin C (mg/l)	37	0.1 (0.2)	40	0.0 (0.4)	0.0 (-0.06 to 0.4)	0.31

eGFR, estimated glomerular filtration rate. \*Calculated on the basis of Modification of Diet in Renal Disease Study criteria.

Table 2: Baseline, change from baseline to 6 months, and difference in change in measured concentrations of eGFR, serum creatinine, and cystatin C for renal denervation and control groups

( $p=0.04$ ). Four (8%) of 49 patients who underwent renal denervation had drug increases prior to the 6-month follow-up, as did six (12%) of 51 controls ( $p=0.74$ ).

In a subanalysis that censored all data after drug increases, we noted blood pressure reduction after 6 months of 31/12 mm Hg (SD 22/11) in patients who underwent renal denervation ( $p<0.0001$  for systolic and diastolic blood pressures) and a change of 0/-1 (20/10) in controls ( $p=0.90$  for systolic blood pressure,  $p=0.61$  for diastolic blood pressure). The absolute difference between groups was 31/11 mm Hg ( $p<0.0001$  for systolic and diastolic blood pressures) for patients who had no drug increases.

There were no serious complications related to the device or procedure. Minor periprocedural events requiring treatment and possibly related to the procedure consisted of one femoral artery pseudoaneurysm that was treated with manual compression, one post-procedural drop in blood pressure resulting in a reduction in antihypertensive drugs, one urinary tract infection, one extended hospital admission for assessment of paraesthesias, and one case of back pain that was treated with analgesics and resolved after 1 month. Seven (13%) of 52 patients who underwent renal denervation had transient intraprocedural bradycardia requiring atropine; none had any sequelae.

Renal function, as assessed by serum creatinine, eGFR, and cystatin C concentrations were unchanged from baseline in both groups at 6 months (table 2). During 6-month follow-up, no patient had a decrease of more than 50% in eGFR, although two patients who underwent renal denervation and three controls had a more than 25% decrease in eGFR.

We calculated a paired baseline and 6-month urine albumin-to-creatinine ratio for 38 patients who underwent renal denervation and 37 controls. The median changes in urine albumin-to-creatinine ratio at 6 months was -3 mg/g (range -1089 to 76) for patients who underwent renal denervation and 1 mg/g (range -538 to 227) for controls ( $p$  for significance=0.26; Wilcoxon test).

Of 49 patients who underwent renal denervation and were assessed at 6 months, 43 had renal imaging at 6 months (37 renal duplex imaging, five MRI, and five CT angiography). One patient had a possible progression of an underlying atherosclerotic lesion, but intervention

was not needed. The stenosis was not at a location where radiofrequency energy was delivered during the procedure.

For the composite cardiovascular endpoint that was assessed at 6 months, we identified five hospital admissions for hypertensive emergency that were unrelated to non-adherence or non-persistence with drugs (three patients who had renal denervation and two controls); no other composite cardiovascular events occurred.

Additional serious adverse events in patients who had renal denervation requiring hospital admission were one patient with nausea and oedema possibly related to underlying hypertension, one patient with hypertension crisis after abrupt stopping of clonidine, one transient ischaemic attack, one hypotensive episode resulting in a reduction of antihypertensive drugs, and one patient received a coronary stent for angina. Two controls had transient ischaemic attacks, and one received a coronary stent for angina.

## Discussion

Our study supports previous uncontrolled investigations<sup>10,11</sup> that showed a significant reduction in blood pressure can be achieved with catheter-based renal denervation in patients whose essential hypertension was uncontrolled despite treatment with three or more antihypertensive drugs (panel). This benefit was evident by the concordance of measurements of office blood pressure, home blood pressure, and 24-h ambulatory blood-pressure monitoring. Measurements made in parallel in the comparator group of patients randomly assigned to continue antihypertensive drug only, without renal denervation, showed no fall in blood pressure over the 6-month follow-up.

In our study, renal denervation led to a reduction in blood pressure of 10 mm Hg or more in 84% of treated patients. Furthermore, the renal denervation procedure was done without any major adverse effects. Imaging of renal arteries for damage showed no evidence of renal artery stenosis or aneurysmal dilatation during the 6-month follow-up. In one patient, possible progression of an underlying atherosclerotic lesion was identified, but required no further intervention.

We showed no changes in measured renal function with denervation, suggesting that the procedure itself and associated haemodynamic changes have no adverse

effects on the kidneys. Importantly, in renal denervation patients with eGFR of 45–60 mL/min per m<sup>2</sup>, there was no evidence of worsening function, suggesting that this procedure is safe even in those with mild-to-moderately impaired renal function. The reduction of blood pressure alone would be expected to beneficially affect renal impairment.<sup>16</sup> Analysis of large populations, followed up for more than 6 months might show renal preservation as a result of enhanced blood pressure control and probably reduced sympathetic outflow to the kidney.

Controls showed no Hawthorne effect after random allocation. Systolic blood pressures of 36 patients reduced to lower than 160 mm Hg during the 2-week screening period (before qualification blood pressure was measured), which was possibly because of a change to their clinical behaviours after enrolment in the trial. Exclusion of these patients from the study led to a control population whose blood pressure, on average, did not change for the 6-month follow-up.

Testing of this novel treatment technique has its theoretical basis in the previous demonstration of blood-pressure reduction with surgical renal denervation in laboratory models of hypertension,<sup>4</sup> and the finding that the sympathetic outflow to the kidneys is commonly activated in patients with essential hypertension.<sup>3,17–21</sup> Catheter-based renal denervation selectively reduces renal sympathetic efferent activity, which is shown by reduction in renal noradrenaline spillover measurements<sup>10,11,22</sup> and is accompanied by an increase in renal blood flow and reduction in plasma renin activity.<sup>10</sup> Reduction of the kidney's contribution to central sympathetic outflow is probably also important. Renal afferent nerve projections to the hypothalamus can stimulate sympathetic outflow, and hence cause rises of blood pressure and systemic vascular resistance.<sup>14,23–25</sup> This CNS input from renal afferent nerves is crucial for production of the sympathetic activation and hypertension found in patients with end-stage renal disease, and is reduced after therapeutic nephrectomy.<sup>6,26</sup> Renal denervation reduces whole-body noradrenaline spillover and reduces sympathetic nerve traffic to the skeletal muscle vasculature, as measured by

muscle sympathetic nerve activity after renal sympathetic denervation.<sup>10,27,28</sup> Thus, ablation of afferent and efferent renal nerves in patients with treatment-resistant hypertension probably contributes materially to the recorded reductions in blood pressure.

One problem is that sympathetic nerve regrowth might mitigate the treatment effect. Although nerve fibres might grow to transplanted organs,<sup>29</sup> recovery of renal sympathetic function in man has not been shown.<sup>30</sup> Furthermore, afferent somatic fibres might never re-establish function as suggested by the absence of angina following cardiac transplantation. In pilot studies,<sup>14</sup> no loss of antihypertensive response was evident with follow up of 2 years.

We anticipate that future trials will address the effectiveness of renal denervation in mild forms of essential hypertension, and in other diseases in which the renal sympathetic outflow was activated, such as cardiac failure,<sup>31</sup> chronic kidney disease,<sup>6,24,26</sup> and cirrhosis with ascites.<sup>22</sup>

Catheter-based renal denervation, done in a multicentre, randomised trial in patients with treatment-resistant essential hypertension, resulted in significant reductions in blood pressure. The magnitude of blood-pressure reduction can be predicted to affect the development of hypertension-related diseases and mortality. The technique was applied without major complications. This therapeutic innovation, based on the described neural pathophysiology of essential hypertension, affirms the crucial relevance of renal nerves in the maintenance of raised blood pressure in patients with hypertension. Catheter-based renal denervation is very beneficial for patients with treatment-resistant essential hypertension.

#### Contributors

MDE was the principal investigator of this trial. MDE, HK, PAS, MPS, RES, and MB wrote the report. JMM did the statistical analysis under supervision of MDE.

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#### Panel: Research in context

##### Systematic review

Catheter-based renal denervation for treatment of hypertension: a new technique for which we identified one observational multicentre safety and proof-of-principle study and one case report<sup>32</sup> in a search of the PubMed database.

##### Interpretation

Our randomised, controlled trial confirms the role of renal sympathetic nerves in essential hypertension and validates a new therapy for treatment-resistant hypertension. The magnitude of blood-pressure reduction can be predicted to have a meaningful effect on cardiovascular mortality and numerous known sequelae of hypertension.

- Melbourne, VIC, Australia), Markus P Schlaich and Murray D Esler (Baker IDI Heart and Diabetes Institute, Melbourne, VIC, Australia), Dierk Scheinert (Universität Leipzig—Herzzentrum, Leipzig, Germany), Thomas Binder (Allgemeines Krankenhaus der Stadt Wien, Vienna, Austria), Andrzej Januszewicz and Adam Witkowski (Samodzielna Pracownia Hemodynamiczna, Warsaw, Poland), Luis M Ruilope (Hospital 12 de Octubre, Madrid, Spain), Robert Whitbourn (St Vincent's Hospital, Melbourne, VIC, Australia), Heike Bruck (Universitätsklinikum Essen, Essen, Germany), Mark Downes (Kent and Canterbury Hospital, Canterbury, UK), Thomas F Lüscher (University Hospital Zurich, Zurich, Switzerland), Alan G Jardine (University of Glasgow, Glasgow, UK), Mark W Webster (Auckland City Hospital, Auckland, New Zealand), Thomas Zeller (Herz-Zentrum Bad Krozingen, Bad Krozingen, Germany), Jerzy Sadowski and Krzysztof Bartus (The John Paul II Hospital, Jagiellonian University, Krakow, Poland), and Paul A Sobotka, Craig A Staley, and Neil C Barman (Ardian, Mountain View, CA, USA). *Data and safety monitoring board (reviewed all serious adverse events):* David P Lee, Ronald M Wittles, and Vivek Bhalla (Stanford University, Stanford, CA, USA). *Biostatistics:* Joseph M Massaro (Harvard Clinical Research Institute, Boston, MA, USA).
- Conflicts of interest**  
MDE has received consulting fees and travel expenses from Ardian; MDE's institution (Baker IDI Heart and Diabetes Institute, Melbourne, VIC, Australia) has received a research grant from Ardian. HK has received travel expenses from Ardian. PAS is an employee of Ardian and has stock options. MPS has received grant support from Ardian and the Australian National Health and Medical Research Council, is a board member of Abbott Hypertension Steering Committee, has received payment for lectures from Abbott, Servier, Boehringer Ingelheim, Novartis, and AstraZeneca, and has received travel expenses from Novartis and AstraZeneca. RES has received grant support from Ardian. MB has received grant support from Ardian, and is a consultant for Servier, Boehringer Ingelheim, and is on the speakers' bureau for Servier, Pfizer, Boehringer Ingelheim, AstraZeneca, and Sanofi.
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## InvestorCenter

Diabetes

## As Diabetes Explodes, Big Pharma Is Gearing Up

by Melly Alazraki Jan 27th 2011 6:00PM

Updated Jan 27th 2011 6:39PM

Diabetes is a growing global scourge, but for Big Pharma it's more of a lifesaver. In the U.S. alone, a whopping 105 million people have diabetes or prediabetes, according to new estimates from the Centers for Disease Control and Prevention. Nearly 26 million Americans have diabetes, a 10% increase from 2008. And an estimated 79 million adults have prediabetes, a staggering 39% increase from 2008. No wonder pharmaceuticals companies are eager to tap the market.

Characterized by high blood-sugar levels, diabetes results from the body's difficulty to produce and/or use insulin -- a hormone that helps the body use blood sugar for energy. Type 1 diabetes develops when the body can no longer make insulin. In Type 2 diabetes, which accounts for 90% to 95% of cases, the body gradually loses its ability to use and produce insulin.



MCT

In prediabetes, which affects 35% of the adult population, blood sugar levels are higher than normal, but not high enough to be diagnosed as diabetes. Prediabetes though, raises a person's risk of Type 2 diabetes.

#### Hefty Price Tag

Despite its growing prevalence, the disease can't be taken lightly. Diabetes is the seventh-leading cause of death in the U.S. and is a major cause of heart disease, stroke and high blood pressure. Diabetes is also the leading cause of kidney failure, nontraumatic feet and leg amputations, nervous system damage and new cases of blindness among adults in the U.S.

All that adds up to a hefty price tag. Diabetes, the CDC says, costs \$174 billion annually. In November, health insurer UnitedHealth Group (UNH) released a study projecting that the disease will cost the nation \$3.35 trillion over the next decade, with diabetes and prediabetes costing almost \$500 billion annually. A 2007 study by the American Diabetes Association estimated that 1 in every 10 health care dollars is attributed to diabetes.

The CDC is working with the National Institute of Health on the National Diabetes Prevention Program, as provided for in the landmark Affordable Care Act. It estimates that if current trends continue, as many as 1 in 3 U.S. adults could have diabetes by 2050. Just in 2010, 1.9 million new cases were diagnosed in adult Americans. The CDC estimates that 84% of adults diagnosed with diabetes take insulin and/or oral medication.

#### The Top-Selling Drugs

In 2009, the U.S. diabetes market grew 17% from 2008, reaching \$14.9 billion, according to data from health care information company IMS Health. Worldwide, the market generated sales of over \$23 billion, according to independent business information provider Visiongain. By 2019, Morningstar projects the worldwide diabetes market, excluding insulin, will grow to over \$55 billion.

That's why pharmaceutical companies, in search for more revenue in light of the many high-price drugs that are coming off patent, are focusing much of their efforts on this growth market. According to IMS Health, the top-selling diabetes drugs in the U.S. now are Takeda's oral drug Actos, with nearly \$1.8 billion in sales in the first half of 2010; Sanofi-Aventis's (SNY) Lantus products, with nearly \$1.5 billion in sales, and Merck's (MRK) Januvia, with \$854 million in sales. The total diabetes market in the first half of 2010 was \$8.7 billion, nearly as much as full-year 2005's market of \$9.3 billion.

Rounding out the top five diabetes drugs in the U.S. are Novo-Nordisk's (NVO) Novolog and Eli-Lilly's (LLY) Humalog, both of which are analog insulin drugs. Other players include Lilly and Amylin's (AMLN) Byetta, which had fourth-quarter 2010 sales of \$174.6 million, and Novo-Nordisk's Victoza, which had sales of roughly \$127 million in the third quarter. Both are antidiabetes hormone analog drugs. And then there's the controversial oral pill Avandia from GlaxoSmithKlin (GSK), whose sales declined to roughly \$112 million in the third quarter.

Drugs that are analogs of human insulin, such as Lantus, held 42% of the U.S. market, followed by so-called glitazones, such as Actos and Avandia, with 28% of the market, and DPP-4 Inhibitors, such as Januvia and Bristol-Myers Squibb's (BMY) and AstraZeneca's (AZN) Onglyza, with 14% of the market, according to IMS Health data.

#### An Epidemic in China and India

Big Pharma continues to push ahead. In January alone, Lilly and Boehringer Ingelheim announced an agreement to jointly develop diabetes compounds. And a new class of drugs, SGLT-2 inhibitors, holds the promise of becoming blockbusters, according to Morningstar, with Bristol and Astra further along in development of these compounds.

But diabetes research isn't necessarily easy. MannKind's (MNKD) inhaled insulin, for one, was rejected last week by the Food and Drug Administration. And when

111-61

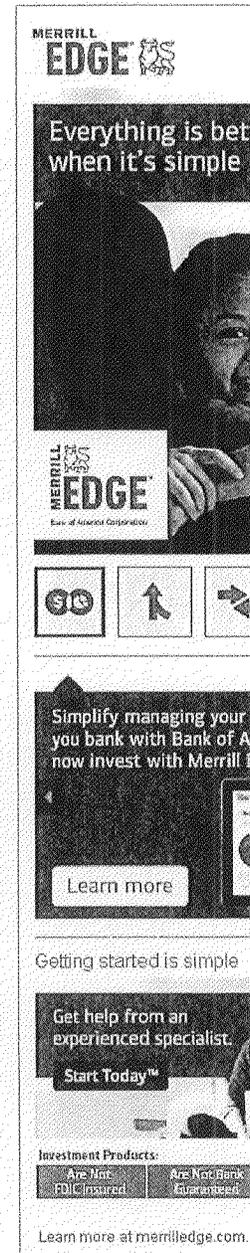
Roche faced setbacks with its once-weekly insulin, it resorted to massive job cuts.

Diabetes is also becoming a global problem, and in some countries, such as China and India, an epidemic. Pharmaceutical companies are paying attention. Lilly recently announced plans to open a research center focused on diabetes in China.

As long as diabetes cases keep expanding, this market will become increasingly important to Big Pharma.

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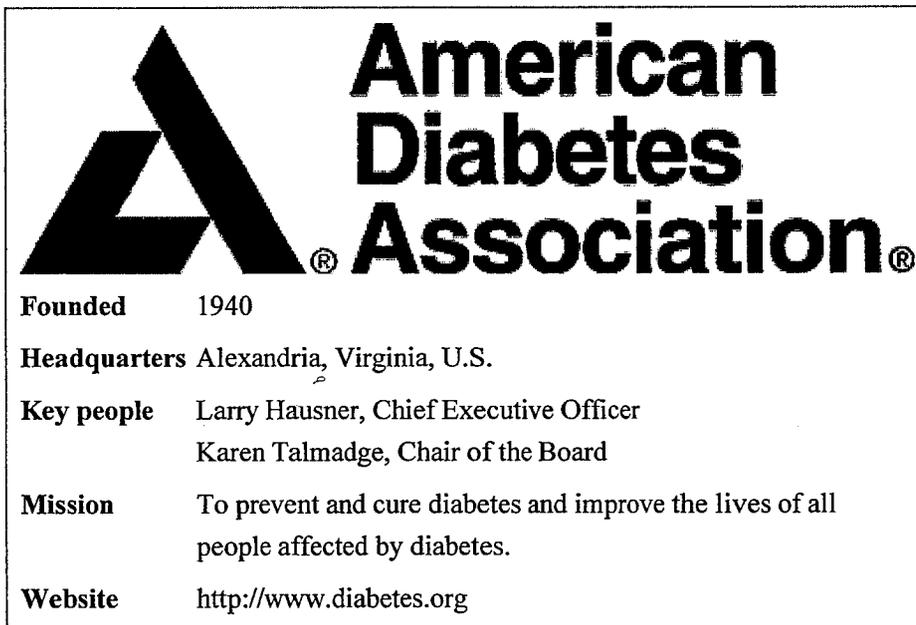
111-62

# American Diabetes Association

From Wikipedia, the free encyclopedia

The **American Diabetes Association (ADA)** is a United States-based association working to fight the consequences of diabetes and to help those affected by diabetes. The Association funds research to manage, cure and prevent diabetes (including type 1 diabetes, type 2 diabetes, gestational diabetes, and pre-diabetes); delivers services to hundreds of communities; provides information for both patients and health care professionals; and advocates on behalf of people denied their rights because of diabetes.<sup>[1]</sup>

## American Diabetes Association



In 2011 it was estimated that 25.8 million Americans have diabetes, and another 79 million have prediabetes.<sup>[1]</sup>

## Contents

- 1 History and mission
- 2 Fund-raising
- 3 Research
  - 3.1 ADA-funded research
  - 3.2 Research Foundation
  - 3.3 Scientific Sessions
- 4 Programs and activities
  - 4.1 Center for Information and Community Support
  - 4.2 Family Link
  - 4.3 Community initiatives
- 5 Events
  - 5.1 Step Out: Walk to Stop Diabetes
  - 5.2 Tour de Cure
  - 5.3 Diabetes EXPO
  - 5.4 School Walk for Diabetes
  - 5.5 BAD Ride
  - 5.6 Father of the Year
- 6 Advocacy

111-63

Obesity

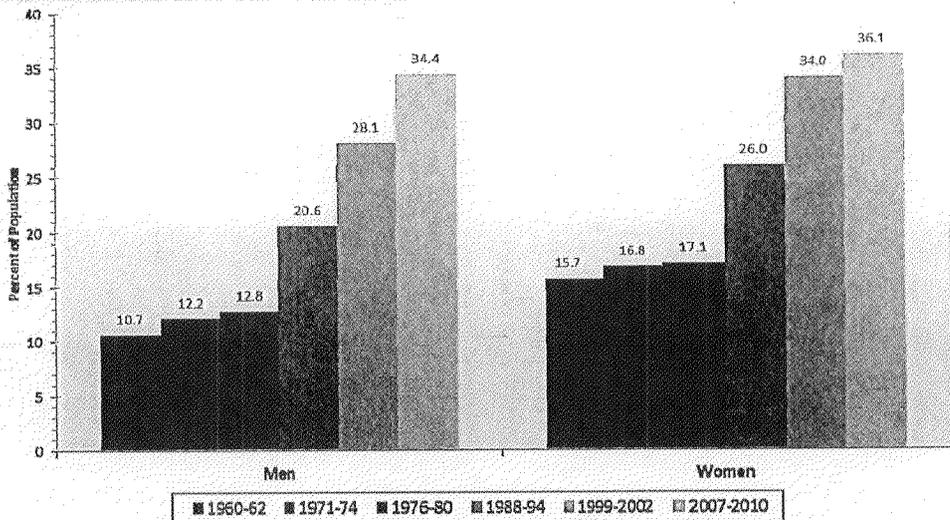


# Overweight & Obesity - 2013 Statistical Fact Sheet

## Adults

- Among Americans age 20 and older, 154.7 million are overweight or obese (BMI of 25.0 kg/m<sup>2</sup> and higher):
  - 79.9 million men.
  - 74.8 million women.
- Of these, 78.4 million are obese (BMI of 30.0 kg/m<sup>2</sup> and higher):
  - 36.8 million men.
  - 41.6 million women.
- Among Americans age 20 and older, the following are overweight or obese (BMI of 25.0 and higher):
  - For non-Hispanic whites, 73.1 percent of men and 60.2 percent of women.
  - For non-Hispanic blacks, 68.7 percent of men and 79.9 percent of women.
  - For Mexican Americans, 81.3 percent of men and 78.2 percent of women.
- Of these, the following are obese (BMI of 30.0 and higher):
  - For non-Hispanic whites, 33.8 percent of men and 32.5 percent of women.
  - For non-Hispanic blacks, 37.9 percent of men and 53.9 percent of women.
  - For Mexican Americans, 36.0 percent of men and 44.8 percent of women.

Age-adjusted prevalence of obesity in adults 20 to 74 years of age



Source: National Health Examination Survey: 1960-1962; National Health and Nutrition Examination Survey: 1971-1974, 1979-1980, 1988-1994, 1999-2002, and 2007-2010; Data derived from Health, United States, 2011 (National Center for Health Statistics).

## Costs

- The total excess cost related to the current prevalence of adolescent overweight and obesity is estimated to be \$254 billion (\$208 billion in lost productivity secondary to premature morbidity and mortality and \$46 billion in direct medical costs).
- If current trends in the growth of obesity continue, total healthcare costs attributable to obesity could reach \$861 to \$957 billion by 2030, which would account for 16% to 18% of US health expenditures.

For additional information, charts and tables, see Chapter 6 of *Heart Disease & Stroke Statistics - 2013 Update*.

Additional charts may be downloaded directly from the online publication at: <http://circ.ahajournals.org/lookup/doi/10.1161/CIR.0b013e31828124ad> Or at: [www.heart.org/statistics](http://www.heart.org/statistics)

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If you have questions about statistics or any points made in the 2013 Statistical Update, please contact the American Heart Association National Center, Office of Science & Medicine at [statistics@heart.org](mailto:statistics@heart.org).

Please direct all media inquiries to News Media Relations at [inquiries@heart.org](mailto:inquiries@heart.org) or 214-706-1173.

111-64

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*154.7 million are overweight or obese*  
*78.4 million are obese*

## Adult Obesity Facts

### Obesity is common, serious and costly

- More than one-third of U.S. adults (35.7%) are obese. [[Read data brief](#)] [[PDF-528Kb](#)] ([/nchs/data/databriefs/db82.pdf](#))
- Obesity-related conditions include heart disease, stroke, type 2 diabetes and certain types of cancer, some of the leading causes of preventable death. [[Read guidelines](#)] ([http://www.nhlbi.nih.gov/guidelines/obesity/ob\\_gdlns.htm](http://www.nhlbi.nih.gov/guidelines/obesity/ob_gdlns.htm)) [[http://www.cdc.gov/Other/disclaimer.html](#)]
- In 2008, medical costs associated with obesity were estimated at \$147 billion; the medical costs for people who are obese were \$1,429 higher than those of normal weight. [[Read summary](#)] (<http://content.healthaffairs.org/cgi/reprint/28/5/w822>) [[http://www.cdc.gov/Other/disclaimer.html](#)]

### Obesity affects some groups more than others

- Non-Hispanic blacks have the highest age-adjusted rates of obesity (49.5%) compared with Mexican Americans (40.4%), all Hispanics (39.1%) and non-Hispanic whites (34.3%) [See *JAMA*. 2012;307(5):491-497. doi:10.1001/jama.2012.39].

### Obesity and socioeconomic status

[[Read data brief](#)] [[PDF-1.07Mb](#)] ([/nchs/data/databriefs/db50.pdf](#))

- Among non-Hispanic black and Mexican-American men, those with higher incomes are more likely to be obese than those with low income.
- Higher income women are less likely to be obese than low-income women.
- There is no significant relationship between obesity and education among men. Among women, however, there is a trend—those with college degrees are less likely to be obese compared with less educated women.
- Between 1988–1994 and 2007–2008 the prevalence of obesity increased in adults at all income and education levels.

[back to top \(/obesity/data/adult.html#top\)](#)

### New baseline established in 2011 for state Obesity rates

- Changes to the CDC's BRFSS ([/surveillancepractice/reports/brfss/brfss.html](#)) and to exclusion criteria result in a new baseline for estimated state adult obesity prevalence starting with the 2011 data. Because of these changes, estimates of obesity prevalence from 2011 forward cannot be compared to estimates from previous years.
- Shifts in estimates from previous years may be the results of the new methods, rather than measurable changes in the percentages. The direction and magnitude of changes in each state varies. These variations may depend on the characteristics of the population.
- State prevalence of obesity remained high across the country in 2011.

*111-65*

**GERD**

**Prevalence:** 63 million people (2000)<sup>11</sup>    **Ambulatory care visits:** 4.0 million (2009)<sup>8</sup>    **Hospitalizations:** 1.1 million (2010)<sup>5</sup>  
**Mortality:** 132 deaths (2010)<sup>10</sup>    **Prescriptions:** 5.3 million (2004)<sup>8</sup>

**Diverticular Disease**

**Prevalence:** 2.2 million people (1998)<sup>12</sup>    **Ambulatory care visits:** 2.7 million (2009)<sup>8</sup>    **Hospitalizations:** 814,000 (2010)<sup>5</sup>  
**Mortality:** 2,889 deaths (2010)<sup>10</sup>    **Prescriptions:** 2.8 million (2004)<sup>8</sup>

**Gallstones**

**Prevalence:** 20 million people (2004)<sup>13</sup>  
**Ambulatory care visits:** 2.2 million (2006–2007)<sup>14</sup> (includes all disorders of the gallbladder and biliary tract)  
**Surgical procedures:** 503,000 (2006)<sup>9</sup> (laparoscopic cholecystectomies only)    **Hospitalizations:** 675,000 (2010)<sup>5</sup>  
**Mortality:** 994 deaths (2010)<sup>10</sup>    **Prescriptions:** 1.65 million (2004)<sup>8</sup>

**Gastroesophageal Reflux Disease**

**Prevalence:** Reflux symptoms at least weekly: 20 percent of the population (2004)<sup>15</sup>    **Ambulatory care visits:** 8.9 million (2009)<sup>8</sup>  
**Hospitalizations:** 4.7 million (2010)<sup>5</sup>    **Mortality:** 1,653 deaths (2010)<sup>10</sup>    **Prescriptions:** 64.6 million (2004)<sup>8</sup>

**Gastrointestinal Infections**

**Prevalence:** Nonfoodborne gastroenteritis: 135 million people (1998)<sup>12</sup>; foodborne illness: 76 million people (1998)<sup>12</sup>  
**Ambulatory care visits:** 2.3 million (2004)<sup>8</sup>    **Hospitalizations:** 487,000 (2010)<sup>5</sup>    **Mortality:** 11,022 deaths (2011)<sup>16</sup>  
**Prescriptions:** 938,000 (2004)<sup>8</sup>

**Hemorrhoids**

**Prevalence:** 75 percent of people older than 45 (2006)<sup>17</sup>    **Ambulatory care visits:** 1.1 million (2009)<sup>8</sup>    **Hospitalizations:** 266,000 (2010)<sup>5</sup>  
**Mortality:** 20 deaths (2010)<sup>10</sup>    **Prescriptions:** 2 million (2004)<sup>8</sup>

**Inflammatory Bowel Disease**

**Ambulatory care visits:** 1.9 million (2009)<sup>8</sup>

**Crohn's Disease**    **Prevalence:** 359,000 people (1998)<sup>12</sup>    **Ambulatory care visits:** 1.1 million (2004)<sup>8</sup>  
**Hospitalizations:** 187,000 (2010)<sup>5</sup>    **Mortality:** 611 deaths (2010)<sup>10</sup>    **Prescriptions:** 1.8 million (2004)<sup>8</sup>

**Ulcerative Colitis**    **Prevalence:** 619,000 people (1998)<sup>12</sup>    **Ambulatory care visits:** 716,000 (2004)<sup>8</sup>  
**Hospitalizations:** 107,000 (2010)<sup>5</sup>    **Mortality:** 305 deaths (2010)<sup>10</sup>    **Prescriptions:** 2.1 million (2004)<sup>8</sup>

**Irritable Bowel Syndrome**    **Prevalence:** 15.3 million people (1998)<sup>12</sup>    **Ambulatory care visits:** 1.6 million (2009)<sup>8</sup>  
**Hospitalizations:** 280,000 (2010)<sup>5</sup>    **Mortality:** 21 deaths (2010)<sup>10</sup>    **Prescriptions:** 5.9 million (2004)<sup>8</sup>

**Liver Disease**

111 - 66

**GASTRODYNE, INC.**  
**Form 1-A Offering Statement**

**EXHIBIT 16**

**SELLING DEALER AGREEMENT**

**We are negotiating with  
Selling Dealers, and the  
Selling Dealer Agreement, if any,  
will be filed by an Amendment.**

**GASTRODYNE, INC.**  
**Form 1-A Offering Statement**

**EXHIBIT 17**  
**WARRANT FORMS**



SHAREHOLDER WARRANT

WARRANT NO.: \_\_\_\_\_ DATE OF ISSUE: \_\_\_\_\_ EXERCISABLE AFTER: \_\_\_\_\_

TO PURCHASE \_\_\_\_\_ SHARES EXPIRATION DATE: \_\_\_\_\_

REGISTERED HOLDER \_\_\_\_\_ EXERCISE PRICE: U.S. \$2.00 PER SHARE

ADDRESS: \_\_\_\_\_

TELEPHONE NUMBER: \_\_\_\_\_ EMAIL: \_\_\_\_\_

HOLDER'S SOCIAL SECURITY OR TAXPAYER I.D. NO. \_\_\_\_\_

This Warrant is exercisable for a Period of Two (2) Years Commencing One (1) Year After its above Date of Issue.

This Warrant is non-transferable and non-assignable by the Holder, except by the laws of will and descent if the holder is or are individual(s) or, if the holder is an entity, only to the successor in ownership of the entity.

This Warrant evidences that the above named person or party is the registered holder ("Holder") of the above numbered Warrant to purchase at a price of U.S. \$2.00 per share (the "Exercise Price") at any time until 5:00 p.m. California time on the above Expiration Date (the "Expiration Date"), up to the number of fully paid and non-assessable Shares of common stock, \$0.001 par value (the "Shares") of Gastrodyne, Inc. (the "Company"), a Nevada corporation, upon delivery to the Company of this Warrant, a properly executed Notice of Election to Exercise all or any portion of the shares then eligible for exercise pursuant to this Warrant and payment of the applicable purchase price by wire transfer or cashier's check, payable to Gastrodyne, Inc. at its principal office. If, after a partial exercise of this Warrant, any Shares remain eligible for exercise under this Warrant, the Company shall deliver, by deposit into the U.S. Mail addressed to the last known address of the Holder, a new Warrant evidencing the number of shares then eligible for exercise thereunder. Please notify us of any change in your address.

After 5:00 p.m., California time, on the Expiration Date, the Holder's right to exercise and purchase any Shares then eligible for exercise under this Warrant shall thereafter be null and void.

This Warrant may be redeemed in whole by the Company, in the sole discretion of the Company, at a price of \$0.001 per Warrant if, at any time during the Warrant's exercise period, prior to the Expiration Date of this Warrant, if the Shares of the Company trade at a

price of \$3.00 or more per Share for a period of five (5) continuous market days upon thirty (30) days prior written notice to the Holder of the Redemption Date, said notice being deposited into the U.S. Mail at the last known address of the Holder. The Company shall deliver to the Holder, within fifteen (15) days following the Redemption Date, a check for the redemption fee for the number of Warrants of the Holder redeemed.

This Warrant contains no anti-dilution provisions, and the Shares issued by the exercise of this Warrant shall each be entitled to one vote per share, shall have no preemptive rights to purchase any additional shares of the Company and the holder of the Shares shall have no right to cumulate its votes in the election of directors of the Company.

Subject to the restriction on the transfer or assignment of this Warrant set forth above, in the event of the death of the Holder or the permitted sale of the entity, the executor of the estate of the Holder or the successor to the entity may duly execute the NOTICE OF TRANSFER OR ASSIGNMENT in the form attached.

The Company may deem and treat the then Holder of this Warrant as the absolute owner of this Warrant (notwithstanding any notation of ownership or other writing thereon made by anyone), for the purpose of any exercise, assignment or transfer thereof, or for any other purpose, and the Company shall not be affected by any notice to the contrary.

In the event the Holder delivers to the Company this Warrant and an executed Notice of Election To Exercise, in the form attached hereto, or presents this Warrant to the Company with an executed Notice of Assignment or Transfer, the Company, if the Holder is or are individuals, the Holder(s) shall present written evidence of his/her relationship to the deceased Holder satisfactory to the Company or, if the Holder is an entity, the signer shall present written evidence of his/her authority to act for the successor entity satisfactory to the Company. If said evidence of authenticity or authority is accepted in good faith by the Company and subsequently proves to be false, the Company having acted in good faith, the Company shall not be liable to the Holder(s) on account of its delivery of Shares or a new Warrant to the person, persons, party or parties directed in the Notice of Election To Exercise or the Notice of Assignment or Transfer, respectively.

IN WITNESS WHEREOF, the Company has caused this Warrant to be duly executed under its corporate seal on the above Date of Issue.

GASTRODYNE, INC.

By: \_\_\_\_\_

Print

Name: \_\_\_\_\_

Attest:

Title: \_\_\_\_\_

By: \_\_\_\_\_

Print

Name: \_\_\_\_\_

Title: \_\_\_\_\_



**NOTICE OF ELECTION TO EXERCISE SHAREHOLDER WARRANT NO. \_\_\_\_\_**

The Undersigned hereby irrevocably elects to exercise the right, represented by Shareholder Warrant No. \_\_\_\_\_, to purchase \_\_\_\_\_ shares of Common Stock, \$0.001 par value (the "Shares") of Gastrodyne, Inc. in accordance with the terms of said Warrant and herewith delivers the Exercise Price of U.S. \$2.00 per Share for an aggregate purchase price of U.S. \$\_\_\_\_\_. The Undersigned requests that a Certificate for such Shares be registered in the name of \_\_\_\_\_, whose address is \_\_\_\_\_ and that the Certificate for said Shares be delivered to said address. The Social Security number or Taxpayer Identification Number of the party to whom the Certificate for the Shares shall be delivered is \_\_\_\_\_.

Print  
Name of  
Holder: \_\_\_\_\_

Signed  
By: \_\_\_\_\_

Signed  
By: \_\_\_\_\_

Print  
Name(s): \_\_\_\_\_  
\_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

(The signature must conform in all respects to the name of the Holder(s) as specified on the face of the Warrant. If signed by a duly authorized officer of the Holder, written evidence of the signer's authority to act for the Holder, satisfactory to the Company, is required.)

# G/D **Gastrodyne, Inc.**

Notice Or Transfer Or Assignment Of Shareholder Warrant No. \_\_\_\_\_, Subject To The Restrictions Contained In The Warrant, Pursuant To The Death Of A Holder Or The Sale Of An Entity Which Is A Holder Of The Above Warrant. Valid Evidence Of The Death Of A Holder Or Of The Sale Of An Entity Which Is The Successor To The Entity Which Was The Holder Of The Above Warrant, Satisfactory To The Company Must Accompany This Notice.

FOR VALUE RECEIVED, on this \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_, \_\_\_\_\_ hereby sells, assigns, and transfers unto: \_\_\_\_\_, whose address is \_\_\_\_\_, \_\_\_\_\_ percent (\_\_\_\_%) of the Holder's right, title and interest in and to Warrant No. \_\_\_\_\_ of Gastrodyne, Inc. and does hereby irrevocably constitute and appoint \_\_\_\_\_, Attorney, to transfer the aforesaid percentage of the Holder's right, title and interest in and to said Warrant on the books of Gastrodyne, Inc., with full power of substitution. The Social Security or Taxpayer I.D. Number(s) of the new Holder(s) are \_\_\_\_\_ and \_\_\_\_\_.

**IN THE EVENT OF THE SALE OF AN ENTITY WHICH WAS THE HOLDER OF THE WARRANT:**

Print Name of Original Holder: \_\_\_\_\_

Signed by the Original Holder: \_\_\_\_\_

Title: \_\_\_\_\_

Print Name of Purchaser of the Original Holder: \_\_\_\_\_

Signed By: \_\_\_\_\_

Print Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

**ATTACH VALID EVIDENCE OF THE ABOVE.**

If the surviving Holder is an individual, valid evidence of the relationship to the deceased Holder acceptable to the Company must be supplied. If signed by a duly authorized officer of the Holder, if the Holder is an entity other than an individual, written evidence of the signer's authority to act for the Holder, acceptable to the Company, must accompany this Warrant.

If the Holder is an individual, tenants in common or joint owners with the right of survivorship, attach written evidence of the death of the holder and written evidence of the identity and the relationship of any joint tenant or owner any immediate member(s) of Holder's family to whom this Warrant is to be transferred or assigned. If the Holder is an entity, attach written evidence of the acquisition of the Holder by the successor.

**IN THE EVENT OF THE DEATH OF A HOLDER:**

Print Name of Original Holder: \_\_\_\_\_

Relationship to Original Holder: \_\_\_\_\_

Signed By: \_\_\_\_\_

Print Name: \_\_\_\_\_

Date: \_\_\_\_\_

**ATTACH VALID EVIDENCE OF THE ABOVE.**



**SELLING DEALER WARRANT**

WARRANT NO.: \_\_\_\_\_ DATE OF ISSUE: \_\_\_\_\_ EXERCISABLE AFTER: \_\_\_\_\_

TO PURCHASE \_\_\_\_\_ SHARES EXPIRATION DATE: \_\_\_\_\_

REGISTERED HOLDER \_\_\_\_\_ EXERCISE PRICE: U.S. \$2.00 PER SHARE

ADDRESS: \_\_\_\_\_

TELEPHONE NUMBER: \_\_\_\_\_ EMAIL: \_\_\_\_\_

HOLDER'S SOCIAL SECURITY OR TAXPAYER I.D. NO. \_\_\_\_\_

**This Warrant is exercisable for a Period of Two (2) Years Commencing One (1) Year After its above Date of Issue.**

**This Warrant is non-transferable and non-assignable by the Holder, except by the laws of will and descent if the holder is or are individual(s) or, if the holder is an entity, only to the successor in ownership of the entity.**

This Warrant evidences that the above named person or party is the registered holder ("Holder") of the above numbered Warrant to purchase at a price of U.S. \$2.00 per share (the "Exercise Price") at any time until 5:00 p.m. California time on the above Expiration Date (the "Expiration Date"), up to the number of fully paid and non-assessable Shares of common stock, \$0.001 par value (the "Shares") of Gastrodyne, Inc. (the "Company"), a Nevada corporation, upon delivery to the Company of this Warrant, a properly executed Notice of Election to Exercise all or any portion of the shares then eligible for exercise pursuant to this Warrant and payment of the applicable purchase price by wire transfer or cashier's check, payable to Gastrodyne, Inc. at its principal office. If, after a partial exercise of this Warrant, any Shares remain eligible for exercise under this Warrant, the Company shall deliver, by deposit into the U.S. Mail addressed to the last known address of the Holder, a new Warrant evidencing the number of shares then eligible for exercise thereunder. **Please notify us of any change in your address.**

**After 5:00 p.m., California time, on the Expiration Date, the Holder's right to exercise and purchase any Shares then eligible for exercise under this Warrant shall thereafter be null and void.**

This Warrant may be redeemed in whole by the Company, in the sole discretion of the Company, at a price of \$0.001 per Warrant if, at any time during the Warrant's exercise period, prior to the Expiration Date of this Warrant, if the Shares of the Company trade at a

price of \$3.00 or more per Share for a period of five (5) continuous market days upon thirty (30) days prior written notice to the Holder of the Redemption Date, said notice being deposited into the U.S. Mail at the last known address of the Holder. The Company shall deliver to the Holder, within fifteen (15) days following the Redemption Date, a check for the redemption fee for the number of Warrants of the Holder redeemed.

This Warrant contains no anti-dilution provisions, and the Shares issued by the exercise of this Warrant shall each be entitled to one vote per share, shall have no preemptive rights to purchase any additional shares of the Company and the holder of the Shares shall have no right to cumulate its votes in the election of directors of the Company.

Subject to the restriction on the transfer or assignment of this Warrant set forth above, in the event of the death of the Holder or the permitted sale of the entity, the executor of the estate of the Holder or the successor to the entity may duly execute the NOTICE OF TRANSFER OR ASSIGNMENT in the form attached.

The Company may deem and treat the then Holder of this Warrant as the absolute owner of this Warrant (notwithstanding any notation of ownership or other writing thereon made by anyone), for the purpose of any exercise, assignment or transfer thereof, or for any other purpose, and the Company shall not be affected by any notice to the contrary.

In the event the Holder delivers to the Company this Warrant and an executed Notice of Election To Exercise, in the form attached hereto, or presents this Warrant to the Company with an executed Notice of Assignment or Transfer, the Company, if the Holder is or are individuals, the Holder(s) shall present written evidence of his/her relationship to the deceased Holder satisfactory to the Company or, if the Holder is an entity, the signer shall present written evidence of his/her authority to act for the successor entity satisfactory to the Company. If said evidence of authenticity or authority is accepted in good faith by the Company and subsequently proves to be false, the Company having acted in good faith, the Company shall not be liable to the Holder(s) on account of its delivery of Shares or a new Warrant to the person, persons, party or parties directed in the Notice of Election To Exercise or the Notice of Assignment or Transfer, respectively.

IN WITNESS WHEREOF, the Company has caused this Warrant to be duly executed under its corporate seal on the above Date of Issue.

GASTRODYNE, INC.

By: \_\_\_\_\_

Print

Name: \_\_\_\_\_

Attest:

Title: \_\_\_\_\_

By: \_\_\_\_\_

Print

Name: \_\_\_\_\_

Title: \_\_\_\_\_



**NOTICE OF ELECTION TO EXERCISE SELLING DEALER WARRANT NO. \_\_\_\_\_**

The Undersigned hereby irrevocably elects to exercise the right, represented by Selling Dealer Warrant No. \_\_\_\_\_, to purchase \_\_\_\_\_ shares of Common Stock, \$0.001 par value (the "Shares") of Gastrodyne, Inc. in accordance with the terms of said Warrant and herewith delivers the Exercise Price of U.S. \$2.00 per Share for an aggregate purchase price of U.S. \$\_\_\_\_\_. The Undersigned requests that a Certificate for such Shares be registered in the name of \_\_\_\_\_, whose address is \_\_\_\_\_ and that the Certificate for said Shares be delivered to said address. The Social Security number or Taxpayer Identification Number of the party to whom the Certificate for the Shares shall be delivered is \_\_\_\_\_.

Print  
Name of  
Holder: \_\_\_\_\_

Signed  
By: \_\_\_\_\_

Signed  
By: \_\_\_\_\_

Print  
Name(s): \_\_\_\_\_  
\_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

(The signature must conform in all respects to the name of the Holder(s) as specified on the face of the Warrant. If signed by a duly authorized officer of the Holder, written evidence of the signer's authority to act for the Holder, satisfactory to the Company, is required.)

# G/D **Gastrodyne, Inc.**

Notice Or Transfer Or Assignment Of Selling Dealer Warrant No. \_\_\_\_\_, Subject To The Restrictions Contained In The Warrant, Pursuant To The Death Of A Holder Or The Sale Of An Entity Which Is A Holder Of The Above Warrant. Valid Evidence Of The Death Of A Holder Or Of The Sale Of An Entity Which Is The Successor To The Entity Which Was The Holder Of The Above Warrant, Satisfactory To The Company Must Accompany This Notice.

FOR VALUE RECEIVED, on this \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_, \_\_\_\_\_ hereby sells, assigns, and transfers unto: \_\_\_\_\_, whose address is \_\_\_\_\_, \_\_\_\_\_ percent (\_\_\_\_%) of the Holder's right, title and interest in and to Warrant No. \_\_\_\_\_ of Gastrodyne, Inc. and does hereby irrevocably constitute and appoint \_\_\_\_\_, Attorney, to transfer the aforesaid percentage of the Holder's right, title and interest in and to said Warrant on the books of Gastrodyne, Inc., with full power of substitution. The Social Security or Taxpayer I.D. Number(s) of the new Holder(s) are \_\_\_\_\_ and \_\_\_\_\_.

**IN THE EVENT OF THE SALE OF AN ENTITY WHICH WAS THE HOLDER OF THE WARRANT:**

Print Name of Original Holder: \_\_\_\_\_

Signed by the Original Holder: \_\_\_\_\_

Title: \_\_\_\_\_

Print Name of Purchaser of the Original Holder: \_\_\_\_\_

Signed By: \_\_\_\_\_

Print Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

**ATTACH VALID EVIDENCE OF THE ABOVE.**

If the surviving Holder is an individual, valid evidence of the relationship to the deceased Holder acceptable to the Company must be supplied. If signed by a duly authorized officer of the Holder, if the Holder is an entity other than an individual, written evidence of the signer's authority to act for the Holder, acceptable to the Company, must accompany this Warrant.

If the Holder is an individual, tenants in common or joint owners with the right of survivorship, attach written evidence of the death of the holder and written evidence of the identity and the relationship of any joint tenant or owner any immediate member(s) of Holder's family to whom this Warrant is to be transferred or assigned. If the Holder is an entity, attach written evidence of the acquisition of the Holder by the successor.

**IN THE EVENT OF THE DEATH OF A HOLDER:**

Print Name of Original Holder: \_\_\_\_\_

Relationship to Original Holder: \_\_\_\_\_

Signed By: \_\_\_\_\_

Print Name: \_\_\_\_\_

Date: \_\_\_\_\_

**ATTACH VALID EVIDENCE OF THE ABOVE.**



**ADDITIONAL SELLING DEALER WARRANT**

WARRANT NO.: \_\_\_\_\_ DATE OF ISSUE: \_\_\_\_\_ EXERCISABLE AFTER: \_\_\_\_\_

TO PURCHASE \_\_\_\_\_ SHARES EXPIRATION DATE: \_\_\_\_\_

REGISTERED HOLDER \_\_\_\_\_ EXERCISE PRICE: U.S. \$2.00 PER SHARE

ADDRESS: \_\_\_\_\_

TELEPHONE NUMBER: \_\_\_\_\_ EMAIL: \_\_\_\_\_

HOLDER'S SOCIAL SECURITY OR TAXPAYER I.D. NO. \_\_\_\_\_

**This Warrant is exercisable for a Period of Two (2) Years Commencing One (1) Year After its above Date of Issue.**

**This Warrant is non-transferable and non-assignable by the Holder, except by the laws of will and descent if the holder is or are individual(s) or, if the holder is an entity, only to the successor in ownership of the entity.**

This Warrant evidences that the above named person or party is the registered holder ("Holder") of the above numbered Warrant to purchase at a price of U.S. \$2.00 per share (the "Exercise Price") at any time until 5:00 p.m. California time on the above Expiration Date (the "Expiration Date"), up to the number of fully paid and non-assessable Shares of common stock, \$0.001 par value (the "Shares") of Gastrodyne, Inc. (the "Company"), a Nevada corporation, upon delivery to the Company of this Warrant, a properly executed Notice of Election to Exercise all or any portion of the shares then eligible for exercise pursuant to this Warrant and payment of the applicable purchase price by wire transfer or cashier's check, payable to Gastrodyne, Inc. at its principal office. If, after a partial exercise of this Warrant, any Shares remain eligible for exercise under this Warrant, the Company shall deliver, by deposit into the U.S. Mail addressed to the last known address of the Holder, a new Warrant evidencing the number of shares then eligible for exercise thereunder. **Please notify us of any change in your address.**

**After 5:00 p.m., California time, on the Expiration Date, the Holder's right to exercise and purchase any Shares then eligible for exercise under this Warrant shall thereafter be null and void.**

This Warrant may be redeemed in whole by the Company, in the sole discretion of the Company, at a price of \$0.001 per Warrant if, at any time during the Warrant's exercise period, prior to the Expiration Date of this Warrant, if the Shares of the Company trade at a

price of \$3.00 or more per Share for a period of five (5) continuous market days upon thirty (30) days prior written notice to the Holder of the Redemption Date, said notice being deposited into the U.S. Mail at the last known address of the Holder. The Company shall deliver to the Holder, within fifteen (15) days following the Redemption Date, a check for the redemption fee for the number of Warrants of the Holder redeemed.

This Warrant contains no anti-dilution provisions, and the Shares issued by the exercise of this Warrant shall each be entitled to one vote per share, shall have no preemptive rights to purchase any additional shares of the Company and the holder of the Shares shall have no right to cumulate its votes in the election of directors of the Company.

Subject to the restriction on the transfer or assignment of this Warrant set forth above, in the event of the death of the Holder or the permitted sale of the entity, the executor of the estate of the Holder or the successor to the entity may duly execute the NOTICE OF TRANSFER OR ASSIGNMENT in the form attached.

The Company may deem and treat the then Holder of this Warrant as the absolute owner of this Warrant (notwithstanding any notation of ownership or other writing thereon made by anyone), for the purpose of any exercise, assignment or transfer thereof, or for any other purpose, and the Company shall not be affected by any notice to the contrary.

In the event the Holder delivers to the Company this Warrant and an executed Notice of Election To Exercise, in the form attached hereto, or presents this Warrant to the Company with an executed Notice of Assignment or Transfer, the Company, if the Holder is or are individuals, the Holder(s) shall present written evidence of his/her relationship to the deceased Holder satisfactory to the Company or, if the Holder is an entity, the signer shall present written evidence of his/her authority to act for the successor entity satisfactory to the Company. If said evidence of authenticity or authority is accepted in good faith by the Company and subsequently proves to be false, the Company having acted in good faith, the Company shall not be liable to the Holder(s) on account of its delivery of Shares or a new Warrant to the person, persons, party or parties directed in the Notice of Election To Exercise or the Notice of Assignment or Transfer, respectively.

IN WITNESS WHEREOF, the Company has caused this Warrant to be duly executed under its corporate seal on the above Date of Issue.

GASTRODYNE, INC.

By: \_\_\_\_\_

Print

Name: \_\_\_\_\_

Attest:

Title: \_\_\_\_\_

By: \_\_\_\_\_

Print

Name: \_\_\_\_\_

Title: \_\_\_\_\_



**NOTICE OF ELECTION TO EXERCISE ADDITIONAL SELLING DEALER WARRANT NO. \_\_\_\_\_**

The Undersigned hereby irrevocably elects to exercise the right, represented by Additional Selling Dealer Warrant No. \_\_\_\_\_, to purchase \_\_\_\_\_ shares of Common Stock, \$0.001 par value (the "Shares") of Gastrodyne, Inc. in accordance with the terms of said Warrant and herewith delivers the Exercise Price of U.S. \$2.00 per Share for an aggregate purchase price of U.S. \$\_\_\_\_\_. The Undersigned requests that a Certificate for such Shares be registered in the name of \_\_\_\_\_, whose address is \_\_\_\_\_ and that the Certificate for said Shares be delivered to said address. The Social Security number or Taxpayer Identification Number of the party to whom the Certificate for the Shares shall be delivered is \_\_\_\_\_.

Print  
Name of  
Holder: \_\_\_\_\_

Signed  
By: \_\_\_\_\_

Signed  
By: \_\_\_\_\_

Print  
Name(s): \_\_\_\_\_  
\_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

(The signature must conform in all respects to the name of the Holder(s) as specified on the face of the Warrant. If signed by a duly authorized officer of the Holder, written evidence of the signer's authority to act for the Holder, satisfactory to the Company, is required.)

# G/D **Gastrodyne, Inc.**

Notice Or Transfer Or Assignment Of Additional Selling Dealer Warrant No. \_\_\_\_\_, Subject To The Restrictions Contained In The Warrant, Pursuant To The Death Of A Holder Or The Sale Of An Entity Which Is A Holder Of The Above Warrant. Valid Evidence Of The Death Of A Holder Or Of The Sale Of An Entity Which Is The Successor To The Entity Which Was The Holder Of The Above Warrant, Satisfactory To The Company Must Accompany This Notice.

FOR VALUE RECEIVED, on this \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_, \_\_\_\_\_ hereby sells, assigns, and transfers unto: \_\_\_\_\_, whose address is \_\_\_\_\_, \_\_\_\_\_ percent (\_\_\_\_%) of the Holder's right, title and interest in and to Warrant No. \_\_\_\_\_ of Gastrodyne, Inc. and does hereby irrevocably constitute and appoint \_\_\_\_\_, Attorney, to transfer the aforesaid percentage of the Holder's right, title and interest in and to said Warrant on the books of Gastrodyne, Inc., with full power of substitution. The Social Security or Taxpayer I.D. Number(s) of the new Holder(s) are \_\_\_\_\_ and \_\_\_\_\_.

**IN THE EVENT OF THE SALE OF AN ENTITY WHICH WAS THE HOLDER OF THE WARRANT:**

**IN THE EVENT OF THE DEATH OF A HOLDER:**

Print Name of Original Holder: \_\_\_\_\_

Print Name of Original Holder: \_\_\_\_\_

Signed by the Original Holder: \_\_\_\_\_

Relationship to Original Holder: \_\_\_\_\_

Title: \_\_\_\_\_

Signed By: \_\_\_\_\_

Print Name of Purchaser of the Original Holder: \_\_\_\_\_

Print Name: \_\_\_\_\_

Signed By: \_\_\_\_\_

Date: \_\_\_\_\_

Print Name: \_\_\_\_\_

**ATTACH VALID EVIDENCE OF THE ABOVE.**

Title: \_\_\_\_\_

Date: \_\_\_\_\_

**ATTACH VALID EVIDENCE OF THE ABOVE.**

If the surviving Holder is an individual, valid evidence of the relationship to the deceased Holder acceptable to the Company must be supplied. If signed by a duly authorized officer of the Holder, if the Holder is an entity other than an individual, written evidence of the signer's authority to act for the Holder, acceptable to the Company, must accompany this Warrant.

If the Holder is an individual, tenants in common or joint owners with the right of survivorship, attach written evidence of the death of the holder and written evidence of the identity and the relationship of any joint tenant or owner any immediate member(s) of Holder's family to whom this Warrant is to be transferred or assigned. If the Holder is an entity, attach written evidence of the acquisition of the Holder by the successor.

**G/D Gastrodyne, Inc.**

**MANUALLY SIGNED COPY**



U.S. Securities & Exchange Commission  
100 F Street  
Washington, DC 20549

Re: Form 1-A Offering Statement pursuant to Regulation A for Gastrodyne, Inc.

Gentlemen:

Enclosed are seven (7) copies of the Form 1-A Offering Statement of Gastrodyne, Inc., pursuant to Regulation A (one copy manually signed) with Exhibits.

We will not use a preliminary (red herring) Offering Circular, and the Offering will not commence until its Date of Qualification. We will add the Qualification Date and the Date of Commencement of Sale when we receive confirmation that the filing has been received by the Commission or Federal Express confirms delivery, if the Commission does not acknowledge the receipt of such filings.

I trust you will find the Offering Statement is complete and in proper order.

Very truly yours,  
GASTRODYNE, INC.

Marvin P. Loeb, Sc.D.  
Chairman & CEO

MPL:rjs

Encls.

cc: Donald Baker, Glenn D. Yeik,  
Jeffrey S. Rudner, Allen C. Ostergar, III, Esq.

5 Holland, Bldg. 223  
Irvine, CA 92618  
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