UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 1
TO
FORM S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

INVO BIOSCIENCE, INC

(Exact name of registrant as specified in its charter)

Nevada	**3841**	**20-4036208**
(State or other jurisdiction of incorporation or organization)	*(Primary Standard Industrial Classification Code Number)*	*(IRS Employer Identification No.)*

407 Rear Mystic Avenue, Suite 34C
Medford, Massachusetts 02155
(978) 878-9505
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Kathleen T. Karloff
Chief Executive Officer
INVO Bioscience, Inc.
407 Rear Mystic Avenue, Suite 34C
Medford, Massachusetts 02155
(978) 878-9505 extension 504
(Name, address, including zip code, and telephone number, including area code, of agent for service)

With copies to:
Scott Museles, Esq.
Brooke Martin, Esq.
Shulman Rogers
12505 Park Potomac Avenue
Potomac, Maryland 20854
(301) 230-5200

Approximate date of commencement of proposed sale to the public: As soon as practicable after this registration statement becomes effective.

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

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier registration statement for the same offering. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐	Accelerated filer ☐	Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☑	Emerging growth company ☐

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered (1)	Proposed Maximum Offering Price Per Share (2)	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee
Common Stock, $0.0001 par value per share	43,397,049	$ 0.34	$ 14,754,996.66	$ 1,788.31

(1) Includes of 4,888,048 shares of common stock issuable upon conversion of convertible promissory notes currently held by the selling stockholders. Pursuant to Rule 416 under the Securities Act of 1933 (the "Securities Act"), as amended, this registration statement includes an indeterminate number of additional shares of common stock of the registrant as may be issued or issuable because of stock splits, stock dividends, stock distributions and similar transactions.

(2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c) under the Securities Act, as amended, based upon the average of the high and low prices of the common stock on July 24, 2019, as reported on the OTCQB Marketplace, which date is within five business days prior to filing this Registration Statement.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion July 29, 2019

PRELIMINARY PROSPECTUS

INVO Bioscience, Inc.

43,397,049 Shares of Common Stock

This prospectus relates to the offering and resale by the selling stockholders (the "Selling Stockholders") identified herein of up to 43,397,049 shares of common stock, par value $0.0001 per share, of INVO Bioscience, Inc., consisting of:

- 4,888,048 shares of common stock issuable upon conversion of outstanding convertible promissory notes with an aggregate principal amount of $520,000;
- 38,509,001 shares of common stock presently outstanding.

We will not receive any proceeds from the sale of the common stock covered by this prospectus. The Selling Stockholders may sell any, all or none of the securities offered by this prospectus and we do not know when or in what quantity the Selling Stockholders may sell their shares of common stock hereunder following the effective date of this registration statement.

The Selling Stockholders may offer and sell the shares in a variety of transactions as described under "Plan of Distribution" beginning on page 19, including transactions on any market on which our common stock is quoted, in privately negotiated transactions or otherwise at market prices prevailing at the time of sale, at prices related to such market prices or at negotiated prices.

Our shares of common stock are traded on the OTCQB Marketplace (the "OTCQB") under the symbol "IVOB". On July 22, 2019, the closing sale price of our common stock was $0.34 per share.

Investing in our common stock involves a high degree of risk. You should consider carefully the "Risk Factors" beginning on page 5 of this prospectus before purchasing any of the shares offered by this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is July 29, 2019

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You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with additional or different information. If anyone provides you with different or inconsistent information, you should not rely upon it. These securities are not being offered in any jurisdiction where the offer is not permitted. You should assume that the information in this prospectus is accurate only as of the date on the front of this prospectus, regardless of the time of delivery of this prospectus or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since these dates.

Except as otherwise indicated herein or as the context otherwise requires, references in this prospectus to "we," "our," "us," or the "Company refers to INVO Bioscience, Inc. a Nevada corporation.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus includes "forward-looking statements" pursuant to Section 27A of the Securities Act, to the extent applicable, that are based on current expectations, estimates, forecasts and assumptions and are subject to risks, uncertainties and changes in circumstances that are difficult to predict. All statements, other than statements of historical fact, contained in this prospectus constitute forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "intend," "might," "will," "should," "could," "would," "expect," "believe," "estimate," "anticipate," "predict," "project," "potential,", "forecast", "seek", "target", or the negative of these terms and variations of these expressions.

Our actual results may differ materially from those contemplated by the forward-looking statements. Furthermore, there may be additional factors not so identified. You should not place undue reliance on our forward-looking statements. As you read this prospectus, you should understand that these statements are not guarantees of performance or results. Further, any forward-looking statement speaks only as of the date on which it is made. We caution that the forward-looking statements included are not exclusive, and new factors may emerge, or changes to the foregoing factors may occur. Except as required by law, we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which it is made or to reflect the occurrence of anticipated events or circumstances. New factors emerge from time to time that may cause our business not to develop as we expect causing actual results to differ materially from those expressed or implied by our forward-looking statements.

Investing in our common stock involves a high degree of risk. In the event any of these risks actually occur, our business, financial condition and/or operations may be materially adversely affected. In such case, the trading price of our common stock could decline and investors could lose all or part of their investment. The risks and uncertainties described herein are not exclusive and are intended to reflect the material risks that are specific to us, to our industry, and related to companies that seek to maintain a class of securities that is registered or quoted on an over-the-counter market.

For a more detailed discussion on factors that may affect our business, see the discussion in the sections "Description of Business," "Risk Factors," and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included herein.

We intend that all forward-looking statements made in this prospectus will be subject to the safer harbor protections of the federal securities laws. The forward-looking statements should be read in conjunction with our consolidated financial statements and notes thereto. We undertake no obligation to revise or publicly release the results of any revision to these forward-looking statements. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this registration statement may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statement.

PROSPECTUS SUMMARY

This summary highlights information described more fully elsewhere in this prospectus and is qualified in its entirety by the more detailed information and financial statements included elsewhere in this prospectus. Before you decide to invest in shares of our common stock, you should read the entire prospectus carefully, including the risk factors, the financial statements and the notes to the financial statements included herein.

The Company

INVO Bioscience's mission is to increase access to care and expand fertility treatment and patient care across the globe. We have developed the INVOcell device (the "INVOcell") and procedure (the "INVO Procedure"), the first Intravaginal Culture (IVC) system granted FDA clearance in the United States, in hopes of providing millions of infertile couples across the globe access to this new infertility treatment. We believe this novel device and procedure provides a more natural, safe, effective and economical fertility treatment compared to current infertility treatments, including in-vitro fertilization ("IVF") and intrauterine insemination ("IUI"). The patented INVOcell is utilized during the incubation of eggs and sperm during fertilization and early embryo development. Unlike conventional infertility treatments such as IVF where the eggs and sperm develop into embryos in a laboratory incubator, the INVOcell utilizes the women's vaginal cavity as an incubator to support a more natural fertilization and embryo development environment. The INVOcell promotes In Vivo conception and early embryo development.

In both current utilization of the INVOcell and in clinical studies, the INVO Procedure has proven to have equivalent pregnancy success rates and live birth rates as the traditional assisted reproductive technique IVF.[1] Additionally, we believe the psychological benefits of the potential mother's participation in fertilization and early embryo development by vaginal incubation are incomparable to traditional IVF treatment. This new technique offers to patients a more natural and personalized way to achieve pregnancy and is simple enough to be performed in an appropriately trained physician's office or in a satellite facility of an IVF center.

For many couples struggling with infertility, access to treatment is often not available. Financial challenges, limited availability of specialized medical care, and religious, social and cultural roadblocks can prevent these couples from realizing their dream to have a baby. There are many benefits to the INVO Procedure, including:

- Reduced risk of errors of incorrect embryo transfers as a result of the embryo development occurring within the patient's womb.
- May be offered in more geographical areas due to a lower cost of equipment to support the procedure.
- Increased patient involvement in the treatment and conception.
- Creation of more natural and environmentally stable incubation process compared to traditional IVF incubation in a laboratory.
- Fewer required office visits for the patients.

On November 2, 2015, INVO Bioscience was notified by the United States Food & Drug Administration that the INVOcell and INVO Procedure were granted De Novo classification allowing the Company to market the INVOcell. The Company has since begun to market and sell the INVOcell in locations across the U.S. and plans on continuing to penetrate the market through 2019 and beyond. As of January 2019 the Company had 89 trained physician offices or satellite facilities of the IVF centers in 20 states across the U.S. where patients can receive the INVO Procedure for infertility. The Company has sold approximately 6,000 INVOcell devices to date since we commenced sales in 2008, of which 3,300 have been sold in the United States since November 2015.

During the first six (6) months of 2018, INVO Bioscience increased its training capacity by offering training by three teams located in San Antonio and Dallas, Texas and Greenville, South Carolina. We provide a one-day session format where it is a collaborative effort between the doctor and their embryology staff providing an overview of the treatment and then hands on training regarding the specific techniques required of the INVO Procedure.

INVO Bioscience, Inc. is a Nevada corporation with its principal executive offices at 407R Mystic Avenue, Suite 34C, Medford, MA 02155. Our telephone number is (978) 878-9505. The address of our website is www.INVOBioscience.com. The information provided on our website is not part of this prospectus and you should not consider the contents of our website in making an investment decision regarding out stock.

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[1] Journal of Assisted Reproduction and Genetics: Comparing Blastocyst Quality and Live Birth Rates of Intravaginal Culture Using INVOcell™ to Traditional in Vitro Incubation in a Randomized Open-Label Prospective Controlled Trial, Kevin J. Doody & E. Jason Broome & Kathleen M. Doody; January 13, 2016. https://invobioscience.com/wp-content/uploads/2016/07/Doody-Report.pdf

Recent Developments

On November 12, 2018, INVO Bioscience, Inc entered into a Distribution Agreement with Ferring International Center S.A. ("Ferring"), pursuant to which, among other things, the Company granted to Ferring an exclusive license in the United States (the "Territory") with rights to sublicense under patents related to the Company's proprietary intravaginal culture device known as INVOcell™, together with the retention device and any other applicable accessories (collectively, the "Licensed Product") to market, promote, distribute and sell the Licensed Product with respect to all therapeutic, prophylactic and diagnostic uses of medical devices or pharmaceutical products involving reproductive technology (including infertility treatment) in humans (the "Field"). Ferring is responsible, at its own cost, for all commercialization activities for the Licensed Product in the Field in the Territory. The Company does retain a limited exception to the exclusive license granted to Ferring allowing the Company, subject to certain restrictions, to establish up to five clinics that will commercialize INVO cycles in the Territory. The Company retains all commercialization rights for the Licensed Product outside of the United States.

Under the terms of the Distribution Agreement, Ferring made an initial payment to the Company of $5,000,000 as a result of completing certain closing conditions, including an agreement from all current manufacturers of the Licensed Product that upon a material supply default by the Company, Ferring can assume a direct purchase relationship with such manufacturers. The Closing of the Distribution Agreement occurred on January 14, 2019. Ferring is obligated to make a second payment to the Company of $3,000,000 provided that the Company is successful in obtaining a five (5) day label enhancement from the FDA for the current incubation period for the Licensed Product at least three (3) years prior to the expiration of the term of the license for the Licensed Product and provided further that Ferring has not previously exercised its right to terminate the Distribution Agreement for convenience. In addition, under the terms of a separate Supply Agreement, attached as an exhibit to the Distribution Agreement, Ferring is obligated to pay the Company a specified supply price for each Licensed Product purchased by Ferring for distribution.

The Distribution Agreement has an initial term expiring on December 31, 2025 and at the end of the initial term it may be terminated by the Company if Ferring fails to generate specified minimum revenues to the Company from the sale of the Licensed Product during the final two years of the initial term. Provided that no such termination occurs at the end of the initial term, thereafter the term of the Distribution Agreement shall automatically be renewed for successive three (3) years terms unless terminated by mutual consent. The Distribution Agreement is subject to termination upon a material breach by either party, or by Ferring for convenience. In addition, if the closing under the Distribution Agreement does not occur within seventy five (75) days, a non-breaching party may elect to terminate the Distribution Agreement.

The INVOcell Technology

Our product, the INVOcell medical device, is designed to treat infertility at a lower cost than other treatments available in today's marketplace, including IVF. The INVOcell technology is a fertility treatment where mild ovarian stimulation is used. Using a mild stimulation protocol, 1-7 follicles are retrieved from a woman in a physician's office with the patient under light sedation with or without local anesthesia. The follicle retrieval is performed using a vaginal probe under ultrasound guidance. Eggs are identified immediately after retrieval in the follicular fluid. During the INVO Procedure, fertilization and embryo development occurs inside the woman's vaginal cavity in a disposable single use device -- the INVOcell -- that holds the eggs, sperm and culture medium, a nutrient liquid.

Sperm collection and preparation generally occur before egg retrieval. Culture medium (~1ml) is placed in the inner vessel of the INVOcell. Eggs and a low concentration of motile sperm are placed into the medium in the inner vessel then the inner vessel is closed and secured in the protective outer vessel. The INVOcell is placed in the patient's vaginal cavity for an incubation period of three (3) days in the United States and five (5) days in other countries. A retention system can be used to maintain the INVOcell system in the vagina during the incubation period. The retention system consists of a diaphragm type device with holes in the membrane to allow natural elimination of vaginal secretions. The INVOcell is designed so that no vaginal fluids penetrate the outer vessel thus ensuring that the inner vessel is not contaminated while allowing the necessary CO2 for fertilization to pass through. The eggs, sperm and media are inserted into the INVOcell and then the INVOcell is placed in the vaginal cavity. This process is expected to take approximately 30 minutes.

After three (3) to five (5) days the patient returns to the physician's office where the retention system and the INVOcell are removed. The protective outer vessel is discarded and the inner vessel is placed in a warming test tube block. The contents of the device are then aspirated and placed into a petri plate whereas the embryologist can evaluate the best embryo(s) for transfer. A trained clinician can readily identify the best embryos for transfer. The embryos to be transferred are aspirated into a standard transfer catheter for transfer into the patient's uterus. This second process is estimated to take approximately 20-30 minutes. All INVO related medical procedures can be performed in a physician's office furnished with the necessary equipment thereby avoiding the requirements of an IVF facility and the associated costs to build and maintain such a facility.

The Offering

We are registering for resale by the Selling Stockholders named herein 43,397,049 shares of our common stock.

Common stock that may be offered by the Selling Stockholders:	Up to 43,397,049 shares of common stock, $0.0001 par value per share, consisting of: ●4,888,048 shares of common stock issuable upon conversion of outstanding convertible promissory notes with an aggregate principal amount of $520,000 (the "Notes"); ●38,509,001 shares of common stock presently outstanding.
Common stock outstanding before this offering:	155,546,112 shares
Common stock to be outstanding after this offering:	160,434,160 shares assuming the issuance of shares of common stock upon the conversion of all of the Notes
Use of proceeds:	We will not receive any proceeds from the sale of the shares of common stock offered by the Selling Stockholders under this prospectus or from the conversion of the Notes.
Risk factors:	Please see the section of this prospectus entitled "Risk Factors" on page 5 for a discussion of factors to carefully consider before deciding to invest in shares of our common stock.
OTCQB Marketplace symbol:	"IVOB"

RISK FACTORS

Investing in our shares of common stock is very risky. Before making an investment decision, you should carefully consider all of the risks described in this prospectus. If any of the risks discussed in this prospectus actually occur, our business, financial condition and results of operations could be materially and adversely affected, the price of our shares could decline significantly, and you might lose all or a part of your investment. The risk factors described below are not the only ones that may affect us. Our forward-looking statements in this prospectus are also subject to the following risks and uncertainties. In deciding whether to purchase our shares, you should carefully consider the following factors, among others, as well as information contained in this prospectus.

Risks Relating to Our Business

Our business has posted net operating losses, has a limited operating history, and needs additional capital to grow and finance its operations.

From the inception of our consolidated subsidiary BioXcell Inc. on January 5, 2007 through March 31, 2019, INVO Bioscience had an accumulated net loss of $22,179,792. INVO Bioscience has a limited operating history and is essentially an early-stage operation. We will continue to be dependent on having access to additional new capital that will allow us to finance operations during our growth. Continued net operating losses together with limited working capital make investing in our common stock a high-risk proposal. The adverse effects of a limited operating history include reduced management insight into future activities, marketing costs, and customer acquisition and retention, which could lead to INVO missing targets for the achievement of profitability.

We may require additional capital to continue executing the Company's business plan which if not obtained could result in a need to curtail or cease operations.

On January 14, 2019, INVO Bioscience entered into a distribution agreement Distribution Agreement with Ferring granted to Ferring exclusive licensing rights to sublicense the Company's INVOcell together with the retention device. Under the terms of the Distribution Agreement, Ferring was obligated to make an initial payment to the Company of $5,000,000 upon satisfaction of certain closing conditions. The Company received the initial $5 million cash payment received upon the execution of the Ferring distribution agreement in January 2019 and as a result believes its cash on hand will be sufficient to fund its current debt obligations, estimated capital expenditures and working capital needs for the next twelve to eighteen months. As of March 31, 2019 the Company had a cash balance of $3,057,466.

However, to continue executing the Company's business plan successfully, the Company may need to raise additional money in the future No assurance can be given that we will be successful in raising capital in the amounts or rate needed, or that such capital, if available, will be available on terms acceptable to the Company. If the Company is not able to raise additional capital at the rate and in the amounts needed, the business may be significantly impacted.

Our business is subject to significant competition.

The infertility industry is highly competitive and characterized by technological improvements and advancements. New assisted reproductive technology ("ART") services, devices and techniques may be developed that may render the INVOcell obsolete. Competition in the areas of infertility and ART services is largely based on pregnancy rates and other patient outcomes. Accordingly, the ability of our business to compete is largely dependent on our ability to achieve adequate pregnancy rates and patient satisfaction levels. Our business operates in highly competitive areas that are subject to continual change. New health care providers and medical technology companies entering the market may reduce our market share, patient volume and growth rates, and could force us to alter our planned pricing. Additionally, increased competitive pressures may require us to commit more resources to our marketing efforts, thereby increasing our cost structure and affecting our ability to achieve, or the timing of achieving, profitability. There can be no assurance that we will be able to compete effectively nor can there be any assurance that additional competitors will not enter the market. Such competition may make it more difficult for the Company to enter into additional contracts with fertility clinics or open profitable INVOcell clinics.

Under the terms of our recently signed U.S., Distribution Agreement, Ferring will handle all sales and marketing activities for the U.S. market and the Company will be allowed to initially open and operate five (5) dedicated INVO clinics. There can be no assurances our U.S., market partner or the Company's own commercial activities will be successful. Additionally, pursuant to the Distribution Agreement, Ferring will have the ability to elect to distribute and commercialize competitive products. The development and commercialization of such competitive products could reduce the Company's U.S. market share.

We need to manage growth in operations to maximize our potential growth.

In order to maximize potential growth in our current and potential markets, we believe the Company must expand the scope of its services in the medical device/bioscience industry. Such expansion will place a significant strain on our management, operational and sales systems. As a result, we plan to continue to improve our INVO technology, operating procedures and management information systems. We will also need to effectively train, motivate and manage our employees. Our failure to manage our growth could disrupt our operations and ultimately prevent us from generating the expected revenues.

We may not be successful in implementing our growth strategy.

Our growth strategy includes growing internally by increasing our target customer base. However, many factors including, but not limited to, increased competition from similar businesses, unexpected costs, costs associated with marketing efforts and maintaining a strong client base may interfere with our ability to expand successfully. There can be no assurance that we will succeed in implementing our strategy in order to establish our services in any additional markets. Our inability to implement this internal growth strategy successfully may have a negative impact on our growth, future financial condition, results of operations and/or cash flows.

We may be unable to implement our strategies in achieving our business objectives.

Our business plan is based on circumstances currently prevailing and the basis and assumption that certain circumstances will or will not occur, as well as the inherent risks and uncertainties involved in various stages of market implementation. However, there is no assurance that we will be successful in implementing our strategies or that our strategies, even if implemented, will lead to the successful achievement of our objectives. If we are not able to implement our strategies successfully, our business operations and financial performance may be adversely affected.

Our products incorporate intellectual property rights developed by us that may be difficult to protect or may be found to infringe on the rights of others.

While we currently own U.S. and international patents, there can be no assurance that any of these patents will not be challenged, invalidated or circumvented, or that any rights granted under these patents will provide competitive advantages. The United States or Europe could place restrictions on the patentability of various medical devices which may materially affect our business. We utilize a combination of trade secrets, confidentiality policies, non-disclosure and other contractual arrangements in addition to relying on patent, copyright and trademark laws to protect our intellectual property rights. However, these measures may not be adequate to prevent or deter infringement or other misappropriation. Further, our intellectual property rights may be found to infringe on intellectual property rights of third parties. Moreover, we may not be able to detect unauthorized use or take appropriate and timely steps to establish and enforce our proprietary rights. Existing laws of some countries in which we conduct business offer only limited protection of our intellectual property rights, if at all. As the number of market entrants as well as the complexity of the technology increases, the possibility of functional overlap and inadvertent infringement of intellectual property rights also increases.

We may be forced to defend our intellectual property rights from infringement through expensive legal action.

Third parties may in the future assert claims against us alleging that our infringement on their intellectual property rights. Defending such claims may be expensive, time consuming and divert the efforts of our management and/or technical personnel. Because of litigation, we could be required to pay damages and other compensation, develop non-infringing products or enter into royalty and/or licensing agreements. However, we cannot be certain that any such licenses, will be made available to us on commercially reasonable terms.

We regard our trade secrets, patents and similar intellectual property as critical to our successful operations. To protect our propriety rights, we rely on patent and trade secret laws, as well as confidentiality and license agreements with certain employees, customers and other third-parties. No assurance can be given that our patents will not be challenged, invalidated, infringed or circumvented. If necessary, we intend to defend our intellectual property rights from infringement through legal action, which could be very costly and could adversely affect our ability to achieve and maintain profitability. Our limited capital resources could put us at a disadvantage if we are required to take legal action to enforce our intellectual property rights.

We face potential liability as a provider of a medical device. These risks may be heightened in the area of artificial reproduction.

The provision of medical devices entails the substantial risk of potential tort injury claims. The Company does not engage in the practice of medicine or assume responsibility for compliance with regulatory requirements directly applicable to physicians. In the event we obtain product liability insurance there can be no assurance such insurance will provide adequate coverage against any potential claims. Additionally, there is no assurance we will be able to obtain such insurance on commercially reasonable terms in the future. Furthermore, any claim asserted against the Company could generate costly legal fees, consume management's time resources, and adversely affect the Company's reputation and business, regardless of the merit or eventual outcome of such claim.

There are inherent risks specific to the provision of infertility and ART services. For example, the long-term effects on women of the administration of fertility medication, integral to most infertility and ART services, are of concern to certain physicians and others who fear the medication may prove to be carcinogenic or cause other medical problems. Additionally, any ban or other limitation imposed by the FDA or other foreign regulatory department on fertility medication and services could have a material adverse effect on our business.

If we fail to maintain adequate quality standards for our products, our reputation and business may be adversely affected and harmed.

Our customers are expecting that our products will perform as marketed and in accordance with industrial standards. We will rely on third-party manufacturing companies and their packaging processes in connection with the production of our products. A failure to maintain product quality standards in accordance with our customer's expectations could result in the loss of demand for our products. Additionally, delays or quality lapses in our production lines could result in substantial economic losses to us. Although we believe that our current quality control procedures adequately address these risks, there can be no assurance that we will not experience occasional or systemic quality lapses in our manufacturing and service operations. Currently, we have limited manufacturing capabilities as we rely on a single manufacturing provider regarding our production process. In the event our manufacturer is unable to produce an adequate supply of products at appropriate quality levels, our growth could be limited and our business may be harmed. If we experience significant or prolonged disturbance in our quality standards, our business and reputation may be harmed, which may result in the loss of customers, our inability to participate in future customer product opportunities and reduced revenue and earnings.

We heavily rely on third party package delivery services, and a significant disruption in these services or significant increases in prices may disrupt our ability to import or export materials, increase our costs and negatively affect our ability to achieve and maintain profitability.

We ship a significant portion of our products to our customers through independent package delivery companies. If any of our key third party package delivery providers experience a significant disruption such that any of our products, components or raw materials cannot be delivered in a timely fashion or such that we incur additional shipping costs that we are unable to recoup, our costs may increase and our relationships with certain customers may be adversely affected. In particular, if our third-party package delivery providers increase prices and we are not able to find comparable alternatives or adjust our delivery network, our profitability could be adversely affected.

We may not be able to develop or continue our business if we fail to retain key personnel.

We substantially rely upon the efforts and abilities of our executive management and directors. The loss of any of our executive officers and/or directors services could potentially have a material adverse effect on our business, operations, revenues and/or prospects. If one or more of these persons were to become unable or unwilling to continue in their present positions, we may not be able to replace them readily or timely, if at all. We do not maintain key man life insurance on the lives of any the Company's executive management or directors.

We will need additional, qualified personnel in order to expand our business. Without additional personnel, we will not be able to expand our business.

Expanding our business requires increasing the number of persons engaged in activities for the sale, marketing, administration and delivery of our products as well as clinical training personnel for the proper training of the INVO Procedures. Upon receiving sufficient additional funding, we are planning to hire employees in these areas. Our ability to attract and hire personnel to fulfill these efforts is dependent on our ability to secure sufficient additional funding. However, there is no assurance we will able to obtain sufficient funding in the future necessary to attract and retain potential employees with the proper background and training matching the skills required for the positions.

Currency exchange rate fluctuations may affect the results of our operations.

We intend to distribute our INVOcell product internationally with all sales, domestic and international, in U.S. dollars. As a result, our operations could be impacted by fluctuations in currency exchange rates, although, such risk should be reduced as a result of our invoicing practices. However, even though we invoice in US dollars, our operations may still be negatively impacted by foreign currency exchange rates in the event the US dollar strengthens and the local currency where the product is being sold weakens. In the event such international patients are unable to afford the associated increase costs, international doctors and clinics may not be able to offer the INVOcell product and procedure. Additionally, as an international business we may be susceptible to adverse foreign currency fluctuations.

We are subject to risks in connection with changes in international, national and local economic and market conditions.

Our business is subject to risks in connection with changes in international, national and local economic and market conditions, including the effects of global financial crises, effects of terrorist acts and war. Such economic changes could negatively impact infertile couples' ability to pay for fertility treatment around the world.

We anticipate that eventually international sales will account for a significant part of our revenue. We will experience additional risks associated with international sales, including:

- political and economic instability;
- export controls;
- changes in international legal and regulatory requirements;
- United States and foreign government policy changes affecting the product marketability; and
- changes in tax laws, duties and tariffs.

Any of these factors could have a material adverse effect on our business, results of operations and financial condition. From 2011 through 2018, we sold products in certain international markets mainly through independent distributors, and we anticipated maintain a similar sales strategy for the foreseeable future. In the event a distributor fails to meet annual sales goals, we may be required to obtain a replacement distributor, which may be costly and difficult to locate. Additionally, a change in our distributors, may increase costs, and create a substantial disruption in our operations resulting loss of revenue.

We sell directly to Ferring in the U.S., and if we want to cease selling to Ferring it may be difficult and expensive to find a replacement.

We sell our products directly to Ferring in the United States market. If Ferring fails to meet its milestones, it may be difficult and costly to locate an acceptable substitute partner.

Our auditors have issued a going concern opinion, and we will not be able to achieve our objectives and will have to cease operations if we cannot adequately fund our operations.

Our auditors issued a going concern opinion in connection with the audit of our annual financial statements for the fiscal year ended December 31, 2018. A going concern opinion means that there is substantial doubt that the company can continue as an ongoing business for the next 12 months. We believe this risk was mitigated with the execution of the Distribution Agreement with Ferring and the receipt of an initial $5 million required payment. The Company believes its cash on hand will be sufficient to fund its current debt obligations, estimated capital expenditures and working capital needs for the next twelve to eighteen months. If we are unable to continue as a going concern, we might have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements. In addition, the inclusion of an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern and our lack of cash resources may materially adversely affect our share price and our ability to raise new capital or to enter into critical contractual relations with third parties. There is no assurance that we will be able to adequately fund our operations in the future.

Risks Related to Our Industry

We are subject to significant domestic and international governmental regulation.

Our business is heavily regulated domestically in the United States and internationally. In the United States the FDA, and other federal, state and local authorizes implement various regulations that subject us to civil and criminal penalties, including cease of operations, in the event we fail to comply. Any such actions could severely curtail our sales and business reputation. In addition, more restrictive laws, regulations or interpretations could be adopted, causing compliance with such regulations to become more difficult or expensive. While we devote substantial resources to ensure our compliance with laws and regulations; the possibility cannot be eliminated that interpretations of existing laws and regulations will result in findings of which we have not complied.

The Company believes that the healthcare industry will continue to be subject to increased regulation as well as political and legal action, as future proposals to reform the health care system are considered by Congress and state legislatures. The Company does not know nor has any control over future changes to health care laws and regulations which may have a significant impact on the business.

We are planning clinical trials related to newer technologies that may prove unsuccessful.

We will be conducting clinical trials related to the expansion of the INVOcell indications resulting in ability to potentially lower the cost of the INVOcell Intravaginal Culture System. While we anticipate positive outcomes of these clinical trials, an unsuccessful trial could adversely impact our ability to receive FDA clearance for the particular indications and products being tested and untimely our ability to expand into potential markets.

Our revenues and operating results could fluctuate significantly from quarter to quarter, which may cause our stock price to decline.

Since our inception, we have recognized minimal revenue. Our results from year-to-year and from quarter-to-quarter have, and are expected to continue to, vary significantly based on ordering cycles of distributors and physicians who utilized for sales, and the payment cycle of such organizations. As a result, we expect period-to-period comparisons of our operating results will not be meaningful and unreliable as an indication of our future performance for any future period.

Changes in the healthcare industry may require us to decrease the selling price for our products or could result in a reduction in the available market size.

Governmental and private sector initiatives in the U.S. and abroad involving trends toward managed healthcare and cost containment could place an emphasis on our ability to deliver more cost-effective medical therapies. The development of ore cost-effective devices could eventuality adversely affect the prices and/or sales of our products. Companies in the healthcare industry are subject to various existing and proposed laws and regulations, in both domestic and international markets, regulating healthcare pricing and profitability. Additionally, there have been third-party payer initiatives to challenge the prices associated with medical products, which if successful, could affect our ability to sell products on a competitive basis in the future.

In the United States, there has been a trend of consolidation among healthcare facilities and purchasers of medical devices, allowing such purchasers to limit the number of suppliers from whom they purchase medical products. As result, it is unknown whether such purchasers will decide to stop purchasing our products or demand discounts on our prices. The pressure to reduce our product prices in response to these industry trends and the decrease in market size could adversely affect our anticipated revenues and profitability of our sales, creating a material adverse effect on our business.

Recent economic trends could adversely affect our financial performance.

Economic downturns and declines in consumption in the healthcare market may affect the levels of both our sales and profitability. If a downturn in economic conditions occurs, or if there is deterioration in financial markets and major economies, our financial performance could be adversely affected. The tightening of credit in financial markets may adversely affect the ability of our customers and suppliers to obtain financing, which could result in a decrease in, or deferrals or cancellations of, the sale of our products and services. In addition, weakening economic conditions may result in a decline in spending for ART and fertility assistance that could adversely affect our business operations and liquidity. We are unable to predict the likely duration and severity of any disruption in the domestic and global financial markets.

Recent health trends could adversely affect our financial performance.

Disease outbreaks and epidemics affecting human health could have a negative impact on our future business operations. Our ability to sell the INVOcell could be adversely affected by an outbreak of certain diseases, such as the Zika virus outbreak, that affect women's health and even more particularly pregnant woman's health. Such outbreaks and epidemics could reduce the demand for ART services including INVO, which ultimately will impact the Company's sales and business operations.

Social media platforms present risks and challenges.

The unauthorized use of certain social media vehicles could result in the improper collection and/or dissemination of personally identifiable information causing brand damage and various legal implications. In addition, negative or inaccurate social media posts or comments about the Company on any social networking site could damage the Company's brand, reputation, and goodwill.

Risks Related to Our Common Stock

The significant number of common shares issuable upon conversion of outstanding notes could adversely affect the trading price of our common shares.

The sale of substantial amounts of our common stock at any particular time could cause the trading price of our common stock to decline significantly. In addition, as of June 30, 2019 we had 4,888,048 shares issuable upon conversion of outstanding notes. If our existing stockholders sell substantial amounts of our common stock, including the shares issued upon the conversion of the notes, in the public market, or if the public perceives that such sales could occur, this could have an adverse impact on the market price of our common stock, even if there is no relationship between such sales and the performance of our business.

Our common stock is subject to risks arising from restrictions on reliance on Rule 144 by shell companies or former shell companies.

Under a regulation of the SEC known as "Rule 144", a person who has beneficially owned restricted securities of an issuer and who is not an affiliate of that issuer may sell them without registration under the Securities Act provided that certain conditions have been met. However, Rule 144 is unavailable for the resale of securities issued by an issuer that is a shell company or that has been at any time previously a shell company. The SEC defines a shell company as a company that has no or nominal operations and either (i) no or nominal assets, (ii) assets consisting solely of cash and cash equivalents, or (iii) assets consisting of any amount of cash and cash equivalent sand nominal other assets. The Company is a former shell company.

The SEC has provided an exception to this unavailability if and for as long as the following conditions are met: (a) the issuer of the securities that was formerly a shell company has ceased to be a shell company; (b) the issuer of the securities is subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act; (c) the issuer of the securities has filed all Exchange Act reports and materials required to be filed, as applicable during the preceding 12 months, other than certain Current Reports on Form 8-k; and (d) at least one (1) year has elapsed form the time the issuer filed current comprehensive disclosure with the SEC reflecting its status as an entity that it is not a shell company.

Because of the Company's prior history as a shell company, stockholders who receive our restricted securities will only be able to sell them pursuant to Rule 144 without registration for only as long as we continue to meet the requirements set forth above. No assurance can be given that we will meet these requirements or that we will continue to do so. Furthermore, any non-registered securities we sell in the future or issue will have limited or no liquidity until and unless such securities are registered with the SEC and/or until we comply with the foregoing requirements.

As a result, it may be harder for the Company to raise funding through the sale of debt or equity securities unless we agree to register such securities with the SEC, which could cause the Company to deploy additional resources. In addition, if we are unable to attract additional capital, it could have an adverse impact on our ability to implement our business plan and/or sustain our operations. Our status as a former "shell company" could prevent us from raising additional funds to develop additional technological advancements, which could cause the value of our securities to decline in value.

The ownership of our common stock is concentrated in a small number of investors, some of whom are affiliated with our Board of Directors and management.

Immediately prior to this offering, our management and Board of Directors, own approximately 23% of the Company's issued and outstanding shares of common stock. By virtue of such holdings, they have the ability to exercise significant influence over the Company's business and fairs, including matters requiring approval by our stockholders including but not limited to the following actions:

- the election of the Board of Directors;
- amending the Company's Articles of Incorporation or bylaws; and
- approving a merger, sale of assets, or other corporate transaction.

As a result, the Company's stock ownership profile may discourage a potential acquirer from seeking to acquire shares of our common stock, which in turn could reduce our stock price.

Our directors have the right to authorize the issuance of shares of our preferred stock and additional shares of our common stock.

Our directors, within the limitations and restrictions contained in our Articles of Incorporation and without further action by our shareholders, have the authority to issue shares of preferred stock from time to time in one or more series and to fix the number of shares and the relative conversion and voting rights, and terms of redemption, liquidation preferences and any other preferences, special rights and qualifications of any such series. While we have no intention of issuing shares of preferred stock at the present time, we continue to seek to raise capital through the sale of our securities and may issue shares of preferred stock in connection with a particular investment. Any issuance of shares of preferred stock could adversely affect the rights of holders of our common stock.

Should we issue additional shares of our common stock at a later time, each investor's ownership interest in our stock would be proportionally reduced.

As a publicly traded company, INVO Bioscience is subject to the reporting requirements of U.S. federal securities laws, which can be expensive.

INVO Bioscience is a public reporting company and, accordingly, is subject to the information and reporting requirements of the Securities Exchange Act of 1934 (the "Exchange Act"), and other federal securities laws, including compliance with the Sarbanes-Oxley Act of 2002. We are required to prepare and file annual and quarterly reports, proxy statements and other information with the SEC and furnishing audited reports. Compliance with such reporting requirements are both timely and costly for the Company. We may need to hire additional financial reporting, internal control, and other finance personnel in order to develop and implement appropriate internal controls and reporting procedures.

Failure to comply with internal control attestation requirements could lead to loss of public confidence in our financial statements and negatively impact our stock price.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, we are required to conduct an annual management assessment of the effectiveness of our internal controls over finical reporting. In connection, our independent registered public accounting firm is required to attest to whether our management's assessment is fairly stated in all material respects and separately report on whether it believes we maintained, in all material respects, effective internal controls over our financial reporting. If we fail to timely develop our internal controls, and management is unable to make this assessment, or, once required, if the independent registered public accounting firm cannot timely attest to this assessment, we could be subject to regulatory sanctions. As a result, a loss of public confidence in our financial controls and the reliability of our financial statements may develop ultimately negatively impacting our stock price and our ability to raise additional capital when and as needed.

Because of the Company's limited resources and limited number of employees, management concluded that, as of September 30, 2018, our internal control over financial reporting is not effective in providing reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles.

We will incur costs and demands upon management as a result of complying with the laws and regulations affecting a public company, which could adversely affect our operating results.

As a public company, we will incur significant legal, accounting and other expenses. In addition, the Sarbanes-Oxley Act of 2002 and the Dodd-Frank Wall Street Reform and Consumer Protection Act, as well as rules implemented by the SEC and the securities exchanges, require certain corporate governance practices for public companies. Our management and other personnel have devoted and expect to continue to devote a substantial amount of time to public reporting requirements and corporate governance. These rules and regulations have significantly increase our legal and financial compliance costs and made some activities more time-consuming and costly. If these costs are not offset by increased revenues and improved financial performance, our financial condition and results of operations may be materially adversely affected. These rules and regulations also make it more difficult and more expensive for us to obtain director and officer liability insurance in the future. Additionally, we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified personnel to serve on our board of directors or as executive officers.

The indemnification rights provided to our directors, officers and employees may result in substantial expenditures by our company and may discourage lawsuits against its directors, officers and employees.

Our Articles of Incorporation and applicable Nevada law provide for the indemnification of our directors, officers, employees. The foregoing indemnification obligations could result in us incurring substantial expenditures to cover the costs of settlement or damage awards against directors, officers and employees, which we may be unable to recoup. These provisions and resultant costs may also discourage us from brining a lawsuit against out directors and officers for breaches of their fiduciary duties, and may similarly discourage the filing of derivative litigation by our stockholders against our directs or officer even though such actions, if successful, might otherwise benefit us and our stockholders.

Our shares of common stock are thinly traded, and the price may not reflect our value; there can be no assurance that there will be an active market for our shares now or in the future.

We have a trading symbol for our common stock ("IVOB"), which permits our shares to be traded on the OTCQB.

Our shares of common stock are thinly traded on the OTCQB, and as such the price, if traded, may not reflect our value. There can be no assurance that there will be an active market for our shares of common stock either now or in the future. The market liquidity will be dependent on, among other things, the perception of our operating business and any steps that our management might take to bring us to the awareness of investors. There can be no assurance given that there will be any awareness generated or, if given, that it will be positive.

Consequently, investors may not be able to liquidate their investment or may be able to liquidate it only at a price that does not reflect the value of the business. If a more active market should develop, the price may be highly volatile. Due to the possibility of our common stock being priced lower than its actual value, many brokerage firms may not be willing to effect transactions in the securities. Even if an investor finds a broker willing to effect a transaction in the shares of our common stock, the combination of brokerage commissions, transfer fees, taxes, if any, and any other selling costs may exceed the selling price. Further, many lending institutions will not permit the use of such shares of common stock as collateral for any loans.

If we fail to remain current on our reporting requirements, we could be removed from the OTCQB, which would limit the ability of broker-dealers to sell our securities and the ability of shareholders to sell their securities in the secondary market.

As a company trading on the OTCQB, we must be reporting issuers under Sections 13 or 15(d) of the Exchange Act, and must be current in their reports under Section 13 of the Exchange Act, in order to maintain price quotation privilege. If we fail to remain current on our reporting requirements, we could be removed from the OTCQB. As a result, the market liquidity for our securities could be adversely affected by limiting the ability of broker-dealers to sell our securities and the ability of shareholders to sell their securities in the secondary market.

Shareholders may be diluted significantly through our efforts to obtain financing and from issuance of additional shares of our common stock, including such issuances of shares for services.

To satisfy certain financial obligations, we have issued and may continue to issue shares of our common stock and we have incurred and may continue to incur debt, which may be convertible into shares of our common stock. We may attempt to raise capital by selling shares of our common stock, possibly with warrants, which may be issued or exercised at a discount to the market price for our common stock. These actions would result in dilution of the ownership interests of existing shareholders, and may further dilute the common stock book value, and that dilution may be material. Such issuances may also serve to enhance existing management's ability to control INVO as the shares may be issued to our officers, directors, new employees, or other related parties.

We have convertible notes outstanding, that could give rise to additional issuances of our common stock, potential dilution of ownership to existing stockholders and volatility in the price of our securities.

As of March 31, 2019, we have outstanding convertible notes with an aggregate principal amount of approximately, $680,000, which are convertible into shares at the following varying conversion prices: notes totaling $645,000 convertible at $0.20 per share, a $25,000 note convertible at $0.03 per share and a $10,000 note convertible at $0.01 per share, subject to adjustment in accordance with the terms of such notes. In the event the convertible notes are converted into shares of common stock, the issuance of shares of our common stock upon such conversion will result in dilution of ownership to existing stockholders.

Our common stock may be subject to the "penny stock" rules of the SEC, which will make the shares of our common stock more difficult to sell.

Our shares of common stock are subject to the "penny stock" rules of the Exchange Act. The Exchange Act defines "penny stock" as any equity security that has a market price of less than $5.00 per share, subject to certain restrictions. We anticipate our common stock may continue to be considered a penny stock in the future.

The penny stock rules require broker-dealers to deliver to potential investors a standardized risk disclosure document prepared by the SEC, which provides information about penny stocks and the nature and level of risks in the penny stock market. The broker-dealer must also provide the potential investor current bid and offer quotations for the penny stock, the compensation of the broker-dealer and its salesperson, and monthly account statements showing the market value of each penny stock held in the investor's account. The bid and offer quotations, and the broker-dealer and salesperson compensation information must be given to the potential investor orally or in writing prior to completing the transaction and must be given to the potential investor in writing before or with the investor's confirmation.

In addition, the penny stock rules require that prior to a transaction the broker-dealer make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written agreement to the transaction. The penny stock rules are burdensome and may reduce purchases of any offerings and reduce the trading activity for shares of our common stock. As long as our shares of common stock are subject to the penny stock rules, the holders of such shares of common stock may find it more difficult to sell their securities.

The market for penny stocks has experienced numerous frauds and abuses, which could adversely affect investors in our stock.

We believe that the market for penny stocks has suffered from patterns of fraud and abuse. We believe that many of these abuses have occurred with respect to the promotion of low price stock companies that lacked experienced management, adequate financial resources, an adequate business plan and/or marketable and successful business or product. Because shares of INVO are penny stocks, the share price for INVO common stock may be adversely affected such frauds and abuses involving other penny stocks.

We do not expect to pay any dividends to shareholders.

To date, we have never declared or paid any dividends to our stockholders. Our board of directors does not intend to distribute dividends in the near future. The declaration, payment and amount of any future dividends will be made at the discretion of the board of directors, and will depend upon, among other things, the results of our operations, cash flows and financial conditions, operating and capital requirements, and other factors as the board of directors considers relevant. There is no assurance that future dividends will be paid to stockholders. In the event dividends are paid to stockholders, there is no assurance with respect to the amount of any such dividend.

We may have difficulty raising necessary capital to fund operations because of the thin market and market price volatility for our shares of common stock.

Throughout 2018 and into 2019, there has been a thin market for our shares, and the market price for our shares has been volatile. In recent years, the securities markets in the U.S. and around the world have experienced a high level of price and volume volatility, and the market price of securities of many companies have experienced wide fluctuations that have not necessarily been related to the operations, performances, underlying asset values or prospects of such companies. For these reasons, we expect our shares of common stock will also be subject to volatility resulting from market forces over which we will have no control. The success of our products and services may be dependent upon our ability to obtain additional financing through debt and equity or other means. The thin market for our shares, and the volatility in the market price for our shares, may adversely affect our ability to raise needed additional capital.

USE OF PROCEEDS

The Company will not receive any proceeds from the sale of shares being sold in this offering, including from any conversion of the convertible notes into shares of our common stock. The Selling Stockholders will receive all of the net proceeds from the sale of shares of our common stock offered pursuant to this prospectus.

PRICE RANGE OF COMMON STOCK

Beginning in 2012, our common stock was quoted on the OTC Pink Tier under the symbol “IVOB”. As of July 2018, our common stock has been traded on the OTCQB under the same symbol “IVOB”. The following table sets forth, for the periods indicated, the range of the quarterly high and low closing price information of our common stock as reported by the OTCQB and the OTC Pink Tier for the applicable periods. The OTC Pink Tier prices do not reflect adjustments for retail mark-ups, mark-downs, or commissions and may not necessarily reflect actual transactions.

Fiscal Period	**2019**		**2018**		**2017**		**2016**	
	High	**Low**	**High**	**Low**	**High**	**Low**	**High**	**Low**
First Quarter	0.44	0.40	0.65	0.10	0.39	0.36	0.41	0.35
Second Quarter	0.44	0.41	0.74	0.51	0.30	0.28	0.39	0.36
Third Quarter			0.53	0.35	0.24	0.20	0.33	0.33
Fourth Quarter			0.50	0.41	0.16	0.12	0.38	0.30

On July 17, 2019 the closing high and low bid prices of our common stock on the OTCQB were $0.35 and $0.31 per share, respectively, and there were approximately 167 holders of record of our common stock with 155,546,112 shares issued and outstanding.

To date, we have never declared or paid any cash dividends on our capital stock. We currently intend to retain any future earnings for funding growth and therefore, do not expect to pay any dividends in the foreseeable future.

There were no repurchases of our equity securities during the year end December 31, 2018 or any subsequent interim period.

SELLING STOCKHOLDERS

The following table presents information regarding the Selling Stockholders and the shares they may offer and sell from time to time under this prospectus. This table is prepared based on information supplied to us by the Selling Stockholder. As used in this prospectus, the term "Selling Stockholder" includes the Selling Stockholder and any donees, pledgees, transferees or other successors in interest selling shares received after the date of this prospectus from a Selling Stockholder as a gift, pledge or other non-sale related transfer. The number of shares in the column "Number of Shares Being Offered" represents all of the shares that the Selling Stockholder may offer under this prospectus. The Selling Stockholders may sell some, all or none of its shares.

Beneficial ownership is determined in accordance with Rule 13d-3(d) promulgated by the SEC under the Exchange Act, as amended. Unless otherwise noted, each person or group identified possesses sole voting and investment power with respect to the shares, subject to community property laws where applicable.

Name of Selling Stockholder	Number of Shares Beneficially Owned Prior to Offering (1)	Maximum Number of Shares of Common Stock to be Sold Pursuant to this Prospectus (1)	Maximum Number of Shares of Common Stock Upon Conversion of the Notes to be Sold Pursuant to this Prospectus (2)	Number of Shares Beneficially Owned After Offering (3)	Percentage of Shares Beneficially Owned After Offering (3)
ABBY MORAN	100,000	100,000	-	-	-
ALBERTO SCIOLA, JR.	15,000	15,000	-	-	-
AMANDA MC. CAFFREY	1,200	1,200	-	-	-
ANNE & JEAN JACQUES GABANELLE JOINT TENTS IN COMMON	4,175,000	4,175,000	-	-	-
ATHENA SAUNDERS	94,231	94,231	-	-	-
ANTHONY ANDERSON	130,900	130,900	-	-	-
BENJAMIN PRIME	45,624	45,624	-	-	-
BRIAN FILES	40,000	10,000	-	30,000	*
BRIAN R. CALL	15,000	5,000	-	10,000	*
BRIGITTE MUSET-RANOUX (4)	1,500,000	1,000,000	-	500,000	*
CLAUDE NUMA JEAN	38,075	15,000	-	23,075	*
CLAUDE RANOUX (5)	24,694,000	1,000,000	-	23,694,000	15.23%
CORY AND CINDY HANGER JOINT TENTS IN COMMON	1,575,000	1,575,000	-	-	-
CYNTHIA AND HENRI JEAN, JOINT TENTS IN COMMON	333,000	125,000	-	208,000	*
DARIAN HENDRICKS	4,000	4,000	-	-	-
DAVID C HUNTER	15,000	15,000	-	-	-
DR. JOSE ROBERTO BONILLA	100,000	100,000	-	-	-
DWIGHT D. VALENTINE	300,000	300,000	-	-	-
ELIZABETH ROGERS	317,817	120,000	-	197,817	*
ELKIN LUCENA	400,000	200,000	-	200,000	*
EMILIE MICHELLE GABANELLE	755,000	755,000	-	-	-
ERIC J HOPKINS	1,196,426	1,196,426	-	-	-
EVELYN OBERG	10,000	10,000	-	-	-
FRANCOIS CLEMENT RANOUX	15,000	15,000	-	-	-
GARRY & TEREZA PRIME CHARITALE TRUST	52,141	52,141	-	-	-
GARRY PRIME	6,952	6,952	-	-	-
GINA CELLA	250,000	250,000	-	-	-

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GREG POTCNER	34,975	8,000	-	26,975	*
GREGORY M. NOVARRO	265,457	70,000	-	195,457	*
HENRI JEAN	1,000,000	1,000,000	-	-	-
HENRY & CYNTHIA JEAN JOINT TENANTS IN COMMON	625,000	625,000	-	-	-
JEANNE OWEN (6)	140,000	140,000	-	-	-
JOHN EDWIN NICHOLS JR	40,000	40,000	-	-	-
JOHN L DETWILER, TRUSTEE OF THE JOHN L. AND SYLVIA F. DETWILER LIVING TRUST	82,667	82,667	-	-	-
JOHN WALSH AND MARTHA WALSH	15,000	15,000	-	-	-
JOSE ROBERTO BONILLA NAVARRETE	100,000	100,000	-	-	-
JOSHUA PRIME	39,106	39,106	-	-	-
KATHLEEN M TRAHAN TTEE U/A DTD 12/01/2008	574,350	200,000	-	374,350	-
KERRY JAMES GEAR II	16,250	16,250	-	-	-
LESTER B. BOELTER, TRANSFER ON DEATH TO TRUSTEES LESTER B. BOELTER TRUST	340,000	340,000	-	-	-
LOIC P. MESTON	100,000	100,000	-	-	-
LUDOVIC MOY, M.D.	213,954	213,954	-	-	-
LYTHAM PARTNERS, LLC	1,780,000	1,780,000	-	-	-
MAMADOU CORA MBAYE	250,000	250,000	-	-	-
MAMADOU CORA MBAYE AND MAME DIOUF JTWROS	50,000	50,000	-	-	-
MARC R. D'ANTONIO	36,740	5,500	-	31,240	*
MARIE HELENE GABANELLE	755,000	755,000	-	-	-
MARK NEWBERT	20,857	20,857	-	-	-
MARTIN LANGLEY	145,244	5,000	-	140,244	*
MCELROY, DEUTSCH, MULVANEY & CARPENTER/PH, LLP	1,906,888	1,906,888	-	-	-
MICHAEL BYINGTON	200,000	200,000	-	-	-
MICHELLE HOSSENLOPP	1,470,000	1,470,000	-	-	-
MIRIAM EPSTEIN	74,000	50,000	-	24,000	*
MR. ROBERT CHICK	10,000	10,000	-	-	-
NANCY HARRINGTON	70,000	70,000	-	-	-
NORMAN D. KARLOFF (7)	76,758	42,083	-	34,675	*
OYEDOTUN AJEWOLE	3,000	3,000	-	-	-
PATRICIA AND RODNEY HANGER JOINT TENTS IN COMMON	1,572,000	1,572,000	-	-	-
PETER CHAPPELL-MAHER	341,000	341,000	-	-	-
PETER PRIME	59,963	59,963	-	-	-
PHILIP WARREN	61,000	50,000	-	11,000	*
PRASHANT MEHTA	368,560	368,560	-	-	-
RAEANNA R SHETRON	7,214	5,000	-	2,214	*
RAYMOND R LEONARDO (8)	500,000	500,000	-	-	-

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ROBERT A. MOTTLA	20,000	20,000	-	-	-
SOPHIE MARIE GABANELLE	755,000	755,000	-	-	-
SRGPE INVESTMENTS 2010, LLC	600,000	600,000	-	-	-
SUPPORTING STRATEGIES, LLC	286,000	286,000	-	-	-
TANYA PRIME	35,091	35,091	-	-	-
TAYLOR JAMIESON KOWBEL	1,516,000	1,516,000	-	-	-
THE ADAM G. PRIME REVOCABLE TRUST	26,071	26,071	-	-	-
THE NEW HAMPSHIRE PRIME FAMILY IRREVOCABLE TRUST	52,142	52,142	-	-	-
THE PRIME FAMILY PHASE 2 CN TRUST	68,100	68,100	-	-	-
THE PRIME FAMILY PHASE 2 TRUST	115,368	115,368	-	-	-
VISTA PARTNERS, LLC	50,000	50,000	-	-	-
WILLIAM F. QUIRK JR	5,682,731	5,682,731	-	-	-
WILLIAM T. MELLO	42,858	42,858	-	-	-
MACH 100LP	-	-	125,000	-	-
JOHN W WINFIELD	-	-	500,000	-	-
MATHEW HAYDEN	268,615	268,615	-	-	-
DAVID NAGELBERG 2003 REVOCABLE TRUST	250,000	250,000	-	-	-
KEITH GUENTHER	500,000	500,000	-	-	-
AARON G L FLETCHER	-	-	75,000	-	-
DIGITAL POWER LENDING LLC	800,000	-	197,500	800,000	*
THOMAS R. HENDRICK	250,000	250,000	-	-	-
ROTTER FAMILY TRUST	-	-	1,250,000	-	-
KENNETH BELEW	-	-	25,000	-	-
JILLIAN BOWDRING (9)	-	-	25,000	-	-
JAMES C BOWDRING (10)	-	-	25,000	-	-
CAROL HICKS	-	-	50,000	-	-
HOLLY HICKS	-	-	25,000	-	-
JOHN SULLIVAN	-	-	50,000	-	-
JAMES BOWDRING (11)	1,369,667	1,166,667	2,540,548	203,000	*
LEO BONAVENTURA	75,000	75,000	-	-	-
JAMES DONAHUE	60,000	60,000	-	-	-
CHARLES MULREY (12)	50,000	50,000	-	-	-
NICHOLAS MULREY (13)	50,000	50,000	-	-	-
PATRICK MULREY (14)	50,000	50,000	-	-	-
NEEOO CHIN	262,500	262,500	-	-	-
MATT RETZLOFF	55,556	55,556	-	-	-
LORI H KAHLER (15)	4,208,530	500,000	-	3,708,530	2.38%
KATHLEEN T. KARLOFF (16)	14,200,183	500,000	-	13,700,183	8.81%
KEVIN DOODY (17)	5,073,197	500,000	-	4,573,197	2.94%
ROBERT J BOWDRING (18)	11,715,924	500,000	-	11,215,924	7.21%
MICHAEL J CAMPBELL (19)	607,800	200,000	-	407,800	*
STEVEN SHUM (20)	600,000	200,000	-	400,000	*

* Less than 1%

(1) Does not include any shares of common stock issued pursuant to the convertible notes.

(2) Includes both shares of common stock issuable upon conversion of the convertible notes purchased by each Selling Stockholder in the April/May 2018 and the 2012 financing.

(3) Assumes the sale of all shares offered by the Selling Stockholders pursuant to this prospectus.

(4) Brigitte Murset-Ranoux is the former wife of Claude Ranoux (5) who was a member of the Board of Directors.

(5) Claude Ranoux was a member of the board of Directors from January 1, 2007 through April 5, 2017. Additionally, he served as the President and Treasurer from January 1, 2007 through September 19, 2016.

(6) Affiliate of a broker-dealer. Certified obtained shares of common stock in ordinary course of business.

(7) Norman Karloff is the former husband of Kathleen Karloff, President, Chief Executive Officer and member of the Board of Directors.

(8) Raymond Leonardo is the son of Lori Kahler, Vice President of Global Operations.

(9) Jillian Bowdring is the niece of Robert J. Bowdring, the Company's acting Chief Financial Officer, acting Principal Accounting Officer and member of the Board of Directors.

(10) James C. Bowdring is the nephew of Robert J. Bowdring, the Company's acting Chief Financial Officer, acting Principal Accounting Officer and member of the Board of Directors.

(11) James Bowdring is the brother of Robert J. Bowdring, the Company's acting Chief Financial Officer, acting Principal Accounting Officer and member of the Board of Directors.

(12) Charles Mulrey is the brother-in-law of Robert J. Bowdring, the Company's acting Chief Financial Officer, acting Principal Accounting Officer and member of the Board of Directors.

(13) Nicholas Mulrey is the nephew of Robert J. Bowdring, the Company's acting Chief Financial Officer, acting Principal Accounting Officer and member of the Board of Directors.

(14) Patrick Mulrey is the nephew of Robert J. Bowdring, the Company's acting Chief Financial Officer, acting Principal Accounting Officer and member of the Board of Directors.

(15) Lori Kahler is the Company's Vice president of Global Operations.

(16) Kathleen T. Karloff is the Company's Chief Executive Officer and a member of the Board of Directors.

(17) Kevin Doody is the Company's Medical Director and a member of the Board of Directors.

(18) Robert J. Bowdring is the Company's Secretary and Treasurer, acting Chief Financial Officer and a member of the Board of Directors.

(19) Michael J Campbell is a member of the Company's Board of Directors.

(20) Steven Shum is a member of the Company's Board of Directors.

PLAN OF DISTRIBUTION

We are registering 43,397,049 shares of common stock under this prospectus on behalf of the Selling Stockholders. Except as described below, to our knowledge, the Selling Stockholders have not entered into any agreement, arrangement or understanding with any particular broker or market maker with respect to the shares of common stock offered hereby, nor, except as described below, do we know the identity of any brokers or market makers that may participate in the sale of the shares.

The Selling Stockholders may decide not to sell any shares. The Selling Stockholders may from time to time offer some or all of the shares of common stock through underwriters, brokers, dealers or agents who may receive compensation in the form of discounts, concessions or commissions from the Selling Stockholders and/or the purchasers of the shares of common stock for whom they may act as agent. In effecting sales, broker-dealers that are engaged by the Selling Stockholders may arrange for other broker-dealers to participate. Any underwriters, brokers, dealers or agents who participate in the distribution of the shares of common stock may be deemed to be "underwriters," and any profits on the sale of the shares of common stock by them and any discounts, commissions or concessions received by any such brokers, dealers or agents may be deemed to be underwriting discounts and commissions under the Securities Act.

The Selling Stockholders and any broker-dealer or agents participating in the distribution of the shares of common stock may be deemed to be "underwriters" within the meaning of Section 2(11) of the Securities Act in connection with such sales. In such event, any commissions paid, or any discounts or concessions allowed to, any such broker-dealer or agent and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Selling Stockholders who are "underwriters" within the meaning of Section 2(11) of the Securities Act will be subject to the prospectus delivery requirements of the Securities Act and may be subject to certain statutory liabilities of, including but not limited to, Sections 11, 12 and 17 of the Securities Act and Rule 10b-5 under the Securities Exchange Act of 1934, as amended, or the Exchange Act.

The Selling Stockholders will act independently of the Company in making decisions with respect to the timing, manner and size of each sale. Such sales may be made, on the over-the-counter market, otherwise or in a combination of such methods of sale, at then prevailing market prices, at prices related to prevailing market prices or at negotiated prices. The shares of common stock may be sold according to one or more of the following methods:

- a block trade in which the broker or dealer so engaged will attempt to sell the shares of common stock as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker or dealer as principal and resale by such broker or dealer for its account pursuant to this prospectus;
- an over-the-counter distribution in accordance with the FINRA rules;
- ordinary brokerage transactions and transactions in which the broker solicits purchasers;
- privately negotiated transactions;
- a combination of such methods of sale; and
- any other method permitted pursuant to applicable law.

The Selling Stockholders may pledge or grant a security interest in some or all of the convertible notes or shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock from time to time pursuant to this prospectus or any amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act, amending, if necessary, the list of selling stockholders to include the pledgee, transferee or other successors in interest as Selling Stockholders under this prospectus. The Selling Stockholders also may transfer and donate the shares of common stock in other circumstances in which case the transferees, donees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

At the time a particular offering of shares of common stock is made, a prospectus supplement, if required, will be distributed, which will set forth the names of the Selling Stockholders, the aggregate amount of shares being offered and the terms of the offering, including, to the extent required, (1) the name or names of any underwriters, broker-dealers or agents, (2) any discounts, commissions and other terms constituting compensation from the selling stockholders and (3) any discounts, commissions or concessions allowed or reallowed to be paid to broker-dealers.

Under the securities laws of some states, the shares of common stock being offered hereby may be sold in such states only through registered or licensed brokers or dealers. In addition, in some states the shares of common stock being offered hereby may not be sold unless such shares have been registered or qualified for sale in such state or an exemption from registration or qualification is available and is complied with.

The Selling Stockholders and any other persons participating in the sale or distribution of the shares will be subject to the applicable provisions of the Exchange Act and the rules and regulations thereunder including, without limitation, Regulation M. These provisions may restrict certain activities of, and limit the timing of, purchases by the Selling Stockholder or other persons or entities. Furthermore, under Regulation M, persons engaged in a distribution of securities are prohibited from simultaneously engaging in market making and certain other activities with respect to such securities for a specified period of time prior to the commencement of such distributions, subject to special exceptions or exemptions. Regulation M may restrict the ability of any person engaged in the distribution of the securities to engage in market-making and certain other activities with respect to those securities. In addition, the anti-manipulation rules under the Exchange Act may apply to sales of the securities in the market. All of these limitations may affect the marketability of the shares and the ability of any person to engage in market-making activities with respect to the securities.

We will pay the expenses of registering the shares of common stock under the Securities Act, including registration and filing fees, printing expenses, administrative expenses and certain legal and accounting fees. The Selling Stockholders will bear all discounts, commissions or other amounts payable to underwriters, dealers or agents, as well as transfer taxes and certain other expenses associated with the sale of their securities.

At anytime a particular offer of the shares of common stock is made, a revised prospectus or prospectus supplement, if required, will be distributed. Such prospectus supplement or post-effective amendment will be filed with the SEC, to reflect the disclosure of required additional information with respect to the distribution of the shares of common stock. We may suspend the sale of shares by the Selling Stockholders pursuant to this prospectus for certain periods of time for certain reasons, including if the prospectus is required to be supplemented or amended to include additional material information.

Once sold under the registration statement of which this prospectus forms a part, the shares of common stock will be freely tradable in the hands of persons other than our affiliates.

DESCRIPTION OF SECURITIES

Our authorized capital stock consists of 200,000,000 shares of common stock, $0.0001 par value and 100,000,000 shares of preferred stock, $0.0001 par value. As of July 22, 2019, there were 155,546,112 shares of our common stock outstanding that were held of record by approximately 167 stockholders, and convertible notes to purchase 4,888,048 shares of common stock were outstanding.

The following description is only a summary. You should also refer to our amended and restated certificate of incorporation and bylaws, both of which have been filed with the SEC as exhibits to our registration statement of which this prospectus forms a part.

Common Stock

Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors, and each holder does not have cumulative voting rights. Accordingly, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they so choose.

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared from time to time by the board of directors out of legally available funds. In the event of our liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock.

Holders of common stock have no preemptive or conversion rights or other subscription rights, and there are no redemption or sinking fund provisions applicable to the common stock. All outstanding shares of common stock are, and the shares of common stock offered by us in this offering, when issued and paid for, will be fully paid and nonassessable. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock which we may designate in the future.

Preferred Stock

The board of directors is authorized, subject to any limitations prescribed by law, without stockholder approval, to issue up to an aggregate of 100,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions granted to or imposed upon the preferred stock, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences. The rights of the holders of common stock will be subject to, and may be adversely affected by, the rights of holders of any preferred stock that may be issued in the future. Issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could have the effect of delaying, deferring or preventing a change in control of INVO Bioscience. We have no present plans to issue any shares of preferred stock.

Convertible Promissory Notes

In April and May 2018, the Company entered into a series of Convertible Note Purchase Agreements, pursuant to which we issued to 16 accredited investors, convertible promissory notes (the "2018 Convertible Notes") with an aggregate principal amount of $895,000. The 2018 Convertible Notes bear interest at the rate of 9% per annum. An aggregate principal amount of $550,000 mature on January 30, 2021, and an aggregate principal amount of $345,000 mature on March 31, 2021. The 2018 Convertible Notes are convertible at a price of $0.20 per share. As of March 31, 2019 four 2018 Notes valued at $250,000 were converted into shares.

At any time following its issuance, the holder of a 2018 Convertible Note may convert the note, in whole or in part, into shares of the Company's common stock at a conversion rate of $0.20, subject to adjustment for stock splits, reverse splits and other similar recapitalization events.

Should the Company complete a subsequent equity financing, the 2018 Convertible Notes will be automatically converted into the equity securities to be sold in the next equity financing at a price equal to 75 % of the price paid per share in such subsequent financing.

The 2018 Convertible Notes, were not registered under the Securities Act, or the securities laws of any state, and were offered and sold in reliance on the exemption from registration under the Securities Act provided by Section 4(a)(2) of the Securities Act and/or Rule 506 of Regulation D promulgated thereunder. The shares of common stock issuable upon conversion of the 2018 Convertible Notes were not registered under the Securities Act, or the securities laws of any state, and were offered and sold in reliance on the exemption from registration under the Securities Act provided by Section 4(a)(2) of the Securities Act and/or Rule 506 of Regulation D promulgated thereunder. Each holder of the 2018 Convertible Notes was an accredited investor (as defined in Rule 501 of Regulation D under the Securities Act) at the time of issuance of the note.

Effect of Certain Provisions of our Amended and Restated Articles of Incorporation and Bylaws and the Nevada Anti-Takeover Provisions

Some provisions of Nevada law and our amended and restated articles of incorporation and bylaws contain provisions that could make our acquisition by means of a tender offer, a proxy contest or otherwise, and the removal of incumbent officers and directors more difficult. These provisions, summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids and to promote stability in our management. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors.

Amended and Restated Articles of Incorporation and Bylaws

Our amended and restated articles of incorporation and bylaws provide for the following:

- *Preferred Stock*. The ability to authorize preferred stock makes it possible for our board of directors to issue one or more series of preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of the Company. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of us.
- *Requirements for Advance Notification of Stockholder Nominations*. Our bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors.
- *Stockholder Meetings*. Our charter documents provide that a special meeting of stockholders may be called only by resolution adopted by the majority board of directors, the chairman of the board of directors or the chief executive officer.
- *Amendment of Bylaws.* Our board of directors have the sole power to amend the bylaws.

Nevada Anti-Takeover Provision

Section 78.438 of the Nevada Revised Statutes ("NRS") prohibits a publicly held Nevada corporation from engaging in a business combination with an interested stockholder, generally a person that together with its affiliates owns or within the last two years has owned 10% of the outstanding voting stock, for a period of two years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner, or falls within certain exemptions under the NRS. As a result of these provisions in our charter documents under Nevada law, the price investors may be willing to pay in the future for shares of our common stock may be limited.

Transfer Agent and Registrar

We have engaged the services of Transfer On Line, Inc. as our transfer agent and registrar.

MANAGEMENTS DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read in conjunction with the financial statements and the notes to those statements included in this prospectus. However, these forward-looking statements involve many risks and uncertainties including those referred to herein. Our actual results could differ materially from those indicated in such forward-looking statements as a result of certain factors, such as those set forth in this prospectus under "Risk Factors". We are under no duty to update any of the forward-looking statements after the date of this registration statement to conform these statements to actual results.

Overview

INVO Bioscience's mission is to increase access to care and expand fertility treatment and patient care across the globe. We have developed the INVOcell device and procedure, the first Intravaginal Culture (IVC) system granted FDA clearance in the United States, in hope of providing millions of infertile couples across the country access to this new infertility treatment. This novel device and procedure provides a more natural, safe, effective and economical fertility treatment compared to current infertility treatments, including in-vitro fertilization ("IVF") and intrauterine insemination ("IUI"). The patented INVOcell device is used for the incubation of eggs and sperm during fertilization and early embryo development. Unlike conventional infertility treatments such as IVF where the eggs and sperm develop into embryos in a laboratory incubator, the INVOcell utilizes the women's vagina as an incubator to support a more natural fertilization and embryo development environment. This novel device promotes in vivo conception and early embryo development.

In both current utilization of the INVOcell and in clinical studies, the INVO Procedure has proven to have equivalent pregnancy success rates as the traditional assisted reproductive technique IVF. Additionally, the psychological benefits of the potential mother's participation in fertilization and early embryo development by vaginal incubation are incomparable to traditional IVF treatment. This new technique offers to patients a more natural and personalized way to achieve pregnancy and is simple enough to be performed in an appropriately trained physician's office or in a satellite facility of an IVF center.

For many couples struggling with infertility, access to treatment is often not available. Financial challenges, limited availability of specialized medical care, religious, social and cultural roadblocks can prevent these hopeful couples from realizing their dream to have a baby. There are many benefits to the INVO Procedure, including:

- Reduces the risk of errors of a wrong embryo transfers since the embryos are never far from the woman.
- Reduces the worry of leaving embryos in an incubator where mix-ups have been known to occur.
- Promotes greater involvement by couples in the treatment and conception.
- Creates a more natural and environmentally stable incubation than traditional IVF incubation in a laboratory.
- Reduces the worry of leaving embryos in an incubator where mix-ups have been known to occur.
- Requires fewer office visits for the couples.

In January 2019, Distribution Agreement with Ferring and as a result took a significant step to strengthen the Company that we believe will allow us to implement our overall business plan. We believe that this strategic partnership with a strong reproductive organization such as Ferring Pharmaceuticals will provide us with the necessary sales and marketing resources within the United States to expand the market and help reach all of those couples not receiving reproductive treatments today. The agreement calls for the issuance of an initial upfront payment of $5 million which we received upon the signing of the agreement and then subsequent licensing fee payment of $3,000,000 that will provide us with a source of non-dilutive financing to execute our plan. Under the terms of the agreement we can pursue developing international markets and as well as partnering and opening up to five INVO-only reproductive centers within the U.S. market. We believe this major milestone and agreement is a critical step that allows the Company to implement its mission of expanding access to care in the fertility marketplace.

Prior to the Ferring agreement, one of the largest challenges that INVO Bioscience faced was raising the appropriate capital to implement its business plan while opening the US market as well as pursuing other opportunities across the globe. With our new Distribution Agreement with Ferring we feel we have eliminated that challenge for the foreseeable future. We believe we have the appropriate funding to execute our business plan over the next 18 months.

We anticipate that we will experience significant quarterly fluctuations in our sales and revenues as a result of the Company's efforts to expand the sales of the INVO technology across the United States and into new markets. Operating results will depend upon the continued rollout of the INVOcell device across the U.S. by Ferring as well the training of international physicians and their staffs' on the INVO procedure. In the current year our operating results will be heavily dependent on Ferring's ability to penetrate the U.S. markets.

For the three months ended March 31, 2019 INVO Bioscience continued for a fifth consecutive quarter with revenue over $100,000. The Company continues to establish a market in the United States for its patented INVO procedure & INVOcell device which is now being offered by clinics in 19 states and as far west as Hawaii. We anticipate Ferring will be able to significantly expand our offering with is sales and marketing resources in the months and years ahead.

This first quarter of 2019 was a transition period for INVO and Ferring as a result of entering into the Distribution Agreement. We had shipped some product in the fourth quarter of 2018 to allow Ferring to meet initial customer demand after the signing of the agreement. However during the first quarter the Company worked closely with Ferring to develop new packaging, labeling and branding for the products. As a result of this re-packaging effort, our actual product revenue was low in the first quarter of 2019. The production of the new Ferring packaged INVOcell was completed in April and the Company has commenced shipments to Ferring beginning in the second quarter. The Company currently has a backlog of orders for Ferring and anticipates it will have a significant increase in revenue during the second quarter of 2019.

The Company received a $5 million license fee from Ferring in exchange for their right to market and distribute INVO products across the United States. The license fee will be accounted for over the course of the seven year agreement; accordingly we will recognize $178,000 per quarter in revenue.

Now that the Company has received funding it has started to execute a number of additional strategic initiatives in its business plan. Currently the Company spends approximately $350,000 per quarter to fund its operations and we plan to continue to control our spending. Our quarterly spending cash will increase as we expand our team and as we use cash to pay our key vendors instead of providing vendors shares of our common stock as we have in the past. During the past quarter we expanded our new product development efforts and worked with Ferring on new packaging and labeling. In addition, our new COO and VP of Product Development started to travel internationally to initiate partnership and distribution discussions with potential organizations in the Middle East, Europe and Asia. We have engaged additional investor relations resources and started to improve some of our internal systems.

Additionally, the Company has worked to improve its balance sheet and settle long overdue liabilities with vendors, current and former employees. Over the past 12 months beginning March 31, 2018 we reduced our notes payable from $350,000 down to $35,000. Additionally, our accrued compensation was reduced from $4,037,000 down to $932,000 through both the payment of cash and issuance of stock.

Our registered independent certified public accountants have stated in their report dated April 16, 2019, filed with the Company's Annual Report on Form 10-K that the Company has a generated negative cash outflows from operating activities, experienced recurring net operating losses, and was dependent on securing additional equity or debt financing to support its business efforts. We continue and expect to continue to generate negative cash outflows from operating activities during 2019 as the business continues to grow. As a result of the execution of the Distribution Agreement with Ferring we now believe we have sufficient capital for at least the subsequent 18 months and will be able to grow the overall business more rapidly, moving it toward the goal of generating positive cash flow from operations, although we make no assurances in this regard.

Sales and Marketing

Our primary focus is the sale of the INVOcell device and training doctors and clinicians in the INVO technology to assist infertile couples in having a baby. We believe that our proven INVOcell procedure is an effective low-cost alternative to current treatments. Along with being offered as an option in traditional IVF clinics, the INVO technique may be provided in a physician's office. Therefore, the INVO device and technique may be offered by physicians around the world to couples who do not have access to IVF facilities. Currently, we are authorized to sell the INVOcell device in the United States as of November 2015 after receiving DeNovo class II clearance from the US Food & Drug Administration (FDA) as well as in certain international markets. As of January 2019 we have an exclusive sales, marketing and distribution agreement with Ferring Pharmaceuticals for the US therefore our primary focus will be in the international markets such as the Middle East, Mexico, Europe and India as well as working on regulatory approvals in the large markets such as China. We have established agreements with distributors and have trained physicians around the world in places such as Canada, South and Central America, India, and Asia.

We anticipate that we will experience quarterly fluctuations in our sales and revenues as a result of our efforts to expand the sales of the INVO technology to new markets. Operating results will depend upon a couple of items, first how quickly Ferring can execute its business plan in the United States and the timing of signing of agreements with new distributors internationally along with the training of the distributors and their staffs in the INVO procedure. Since 2016 we had focused our efforts in the US and now with Ferring taking on that role for us as of January 2019, we will focus on supporting Ferring and targeting key markets t outside of the US. We expect International sales will continue to expand in the coming years. As we are just beginning to get into these markets both US and International sales are difficult to forecast as we do not have any significant history to support our assumptions. We are committed to our ongoing sales, marketing and development activities to sustain and grow our sales and revenues from our products and services. However, there can be no assurance that we will be successful in doing so.

During 2017 and 2018, the Company has marketed its products strategically utilizing its limited resources in the most economical fashion possible. We focused most of our efforts on starting the sales in the United States after the FDA clearance in November 2015.

Pursuant to the Distribution Agreement, Ferring is responsible, at its own cost, for all commercialization activities for the Licensed Product in the Field in the United States. The Company does retain a limited exception to the exclusive license granted to Ferring allowing the Company, subject to certain restrictions, to establish up to five clinics that will commercialize INVO cycles in the Territory. We will be looking to work with current doctors in areas of the US where there is demand but currently no IVF facilities. This approach may take many different forms all of which we are willing to explore. The Company retains all commercialization rights for the Licensed Product outside of the United States. As a result of this new agreement we will be changing our focus in 2019 to support Ferring in the United States and increase our efforts in the marketing and sale of the INVOcell in international markets.

INVO Bioscience attended the American Society of Reproductive Medicine (ASRM) Congress's over the past few years starting in Baltimore MD in October 2015. The 2018 ASRM Congress was held in Denver, CO and at times we had a waiting line of interested doctors and embryologists at our booth as we discussed the advantages of INVO. The ASRM Congress is a global meeting and doctors from many international countries showed an interest. The INVOcell continues to be well received by many physicians, embryologists and distributors. During these conferences, we have established many contacts and potential interested parties to assist us expand the sale of the INVOcell worldwide.

Starting in November 2016 and through 2018 the Company changed its training process to a more consistent one. Dr. Kevin Doody of CARE in Bedford, Texas assumed the role of our Medical Director. Dr. Doody and his team held the first training session at his facility for a group of doctors and embryologists recruited during the 2016 ASRM Congress. The training was very successful and the participants were positive about offering INVO to their patients. We found this model to provide a standard process that does not have to be adapted to each facility. The training program allows all of the physicians and embryologists to collaborate and discuss ideas of how they are doing things today compared to the new INVO protocol. It is a free flowing discussion with hands on learning. Dr. Doody will continue in this capacity with Ferring as we move forward together.

The current physicians and embryologists utilizing our solution are very pleased with results they are experiencing with the INVOcell device and INVO Procedure. Many stated that the embryos they are seeing are healthy and strong and in some cases better than the ones they have been developing in their IVF processes. They are also stating they are achieving equal to or better efficacy rates. The doctors believe these are both related to the fact that the embryos are developing as the woman goes about her normal routines and body temperature fluctuations, so there is body & temperature movement, it is not a constant as it would be in an incubator. A good number of the practices are starting to order larger quantities on a more regular basis.

The Company's main focus throughout 2019 will be to focus on the international market. As mentioned above we have hired an IVF sales and marketing professional to support the international efforts.

In the second quarter of 2016, the first post-FDA cleared US baby from the INVOcell and INVO procedure was born in Texas.

Physicians outside the United States have demonstrated that their patients would like to see current success rates within their own geographic and cultural areas. We have and will continue to assist them in sponsoring clinical and marketing trials for "in-country" data. One of the things we have found is that, without an INVO Bioscience employee or representative "in country" focused on the INVO technology, our sales and opportunities were limited. With the hiring of the new Business Development VP, who has built a strong foundation of relationships over the years in the international IVF market, we believe we will make progress in penetrating international markets in 2019.

Operations

We operate by outsourcing many key operational functions in the development and manufacturing of the INVOcell device and its associated products to keep fixed costs to a minimum. Our most critical management and leadership functions are carried out by our core team. We have contracted out the following functions: manufacturing, packaging/labeling and sterilization of the device to a certified manufacturer to mold the parts; to a medical manufacturing company to assemble packages and label the product and to a sterilization specialist to perform the gamma sterilization process. This expedites production and eliminates the need for in-house capital equipment expenditures.

Our most significant challenge in growing our business has been our limited resources. As of December 31, 2018, we generally require approximately $200,000 per month to fund our current normal operations. Over the prior years we had reduced this by, among other things, officers and directors foregoing salaries and fees and not engaging in certain activities so that we could avoid incurring certain expenses (such as travel and marketing costs). As a result of the Ferring agreement and upfront payment, we anticipate our expenses will increase as we expand our sales and marketing efforts and develop new products and services. Our cash needs are primarily attributable to funding our sales and marketing efforts, strengthening our training capabilities, satisfying existing obligations, funding a future U.S. FDA clinical trial for additional product indications, and building an administrative infrastructure, including costs and professional fees associated with being a public company.

We believe we are taking the necessary steps to ultimately provide the company with the capital resources we need to execute our business plan and grow the business.

The exact amount of additional funds we are able to raise, if any, will determine how aggressively we can continue to grow, what additional projects we will be able to undertake, and when. No assurance can be given that we will be able to raise any additional capital. If we are unable to raise additional capital, we may be required to slow down some activities.

Selling, general and administrative expenses were approximately $3,038,068 and $870,612 respectively for the years ended December 31, 2018 and 2017. Throughout this period, we continued to control our spending and use our resources carefully. The $2,167,456 increase in selling, general and administrative expenses in 2018 was the result of the Board of Directors issuing shares to the Board itself and consultants, including a one- time issuance with a value of $1,530,000 for pre and post FDA clearance support services for a total of $1,850,000 during 2018. 876,672 shares were issued in 2017 with a value of $215,132 for services.

Throughout the period 2017 to 2018 we incurred annual net losses as we continued to market our product and proprietary process as we endeavored to increase our revenue base. It is expected that we will continue to generate net losses through 2019.

We cannot accurately predict what our level of activity will be over the next 12-24 months. However, INVO Bioscience anticipates that it will continue to launch the sale of the INVOcell device and INVO procedure in the U.S. through our agreement with Ferring Pharmaceuticals, and in the Mideast, Asia, South America, and India through new distributor partnerships, IVF centers and physicians.

To achieve this plan, we may additional financing. As we expand our distribution base, our costs and expenses may exceed the cash flow being generated and therefore we may require additional capital. There is no guaranty that we will be able to raise any additional financing or when, or that we will be able to raise such funds on terms acceptable to us.

Due to our early stage of growth, our Statement of Operations may not be indicative of future levels of activity. As such, we expect our costs and losses to increase in future periods as we seek to ramp up sales and incur infrastructure costs. As we move forward, the Company expects to expand its sales force and clinical trainers, and to continue to travel to support our distributors and physicians.

The amounts and timing of our actual expenditures may vary significantly from our expectations depending upon numerous factors, including our results of operation, financial condition and capital requirements.

For the years ended December 31, 2018 and 2017, we had net losses of approximately $3,076,000 and $702,000, respectively. The net loss in 2018 was significantly higher than 2017 due to the Company issuing shares to certain Board Members and our Medical Director who were compensated in shares with a value of $1,530,000 for services provided during and following the FDA review and acceptance. We had significant working capital deficiencies in both 2018 and 2017 of $2,770,000 and $4,892,000 respectively. As of December 31, 2018 our stockholder's deficiency was $2,724,000 compared to $4,992,000 as of December 31, 2017 and cash used in operations was $653,000 for 2018 compared to $181,000 for the year ended December 31, 2017. This raises substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern is dependent on, among other things, our ability to raise additional capital and implement our business plan. See "Risk Factors." Our financial statements attached do not include any adjustments that might be necessary if we are unable to continue as a going concern. We finalized our new distribution and supply agreements with Ferring on January 14, 2019 and as part of the closing process the Company received a $5 million one-time license payment. We believe this along with our anticipated sales from the agreement as well as other revenues will provide the Company with cash resources it needs for the next 12-24 months. We may continue to seek alternative funding to execute our longer term business plan.

Critical Accounting Policies and Estimates

The discussion and analysis of INVO Bioscience's financial condition presented in this section are based upon the unaudited and audited consolidated financial statements of INVO Bioscience, which have been prepared in accordance with the generally accepted accounting principles in the United States. During the preparation of the financial statements, INVO Bioscience is required to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. Our estimates include those related to revenue recognition, the valuation of inventory, and valuation of deferred tax assets and liabilities, useful lives of intangible assets, warranty obligations and accruals. On an ongoing basis, INVO Bioscience evaluates based on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. A summary of significant accounting policies is included below. Management believes that the application of these policies on a consistent basis enables us to provide useful and reliable financial information about our operating results and financial condition.

Stock Based Compensation

The Company accounts for stock-based compensation under the provisions of ASC 718-10 Share-Based Payment (formerly SFAS 123R). This statement requires the Company to measure the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost is recognized over the period in which the employee is required to provide service in exchange for the award, which is usually immediate but sometimes over a vesting period. Warrants granted to non-employees are recorded as an expense over the requisite service period based on the grant date estimated fair value of the grant, determined using the Black-Scholes option pricing model.

Revenue Recognition

The Company recognizes revenue on arrangements in accordance with ASU No. 2014-09, Revenue from Contracts with Customers ("ASU 2014-09"). The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services

Recent Accounting Pronouncements

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers ("ASU 2014-09"). The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. The standard is effective for annual periods beginning after December 15, 2017, and interim periods therein.

ASU 2014-09 supersedes existing guidance on revenue recognition with a five-step model for recognizing and measuring revenue from contracts with customers. The objective of the new standard is to provide a single, comprehensive revenue recognition model for all contracts with customers to improve comparability within industries, across industries, and across capital markets. The underlying principle is that an entity will recognize revenue to depict the transfer of goods or services to customers at an amount that the entity expects to be entitled to in exchange for those goods or services. The guidance also requires a number of disclosures regarding the nature, amount, timing, and uncertainty of revenue and the related cash flows. The guidance can be applied retrospectively to each prior reporting period presented (full retrospective method) or retrospectively with a cumulative effect adjustment to retained earnings for initial application of the guidance at the date of initial adoption (modified retrospective method). The Company adopted the new standard effective January 1, 2018 using the modified retrospective method applied to those contracts that were not completed or substantially completed as of January 1, 2018. The timing and measurement of revenue recognition under the new standard is not materially different than under the old standard. The adoption of the new standard did not have an impact on the Company's consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, Improvements to Employee Share-Based Payment Accounting, which intends to simplify several aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, a choice to recognize gross stock compensation expense with actual forfeitures recognized as they occur, as well as certain classifications on the statement of cash flows. The Company adopted this ASU in Fiscal 2018 and it did not have a material impact on the Company's consolidated financial position, results of operations or cash flows.

In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230) ("ASU 2016-18"). The updated standard requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 is effective for public business entities for annual reporting periods beginning after December 15, 2017, including interim periods within those annual reporting periods. The Company adopted ASU 2016-18 as of January 1, 2018. The adoption of ASU 2016-18 did not have a material effect on the Company's consolidated financial statements.

In May 2017, the FASB issued ASU 2017-09, Compensation – Stock Compensation (Topic 718) ("ASU 2017-09"). The updated standard clarifies when an entity must apply modification accounting to changes in the terms or conditions of a share-based payment award. ASU 2017-09 is effective for public business entities for annual reporting periods beginning after December 15, 2017, including interim periods within those annual reporting periods. Early adoption is permitted. The Company adopted ASU 2017-09 as of January 1, 2018. The adoption of ASU 2017-09 did not have a material effect on the Company's consolidated financial statements.

In July 2017, FASB issued ASU 2017-11 (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception ("ASU 2017-11"). The new standard simplifies the accounting for certain financial instruments with down round features. Part I of ASU 2017-11 changes the classification analysis of certain equity-linked financial instruments, such as warrants and embedded conversion features, such that a down round feature is disregarded when assessing whether the instrument is indexed to an entity's own stock under Subtopic 815-40, Contracts in Entity's Own Equity. As a result, a down round feature, by itself, no longer requires an instrument to be re-measured at fair value through earnings each period, although all other aspects of the indexation guidance under Subtopic 815-40 continue to apply. Part II of ASU 2017-11 re-characterizes the indefinite deferral of certain provisions of Topic 480, Distinguishing Liabilities from Equity, (currently presented as pending content in the Codification) as a scope exception. No change in practice is expected as a result of these amendments. The new standard is effective for fiscal years beginning after December 15, 2018, early adoption is permitted. The amendments in Part II have no accounting impact and therefore do not have an associated effective date. The Company decided to early adopt this ASU 2017-11 and applied it to the convertible notes it issued during the year which are reflected in this Form 10K.Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting. In May 2017, the FASB issued ASU No. 2017-09 which was issued to clarify and reduce both (i) diversity in practice and (ii) cost and complexity when applying the guidance in Topic 718, "Compensation – Stock Compensation" to changes in the terms and conditions of a share-based payment award. This update is effective for the Company in the fiscal year beginning October 1, 2018. The adoption of this standard is not expected to have a material impact on the Company's consolidated financial position, results of operations, or cash flows.

Leases (Topic 842). In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842), which requires lessees to put most leases on their balance sheets by recognizing a lessee's rights and obligations, while expenses will continue to be recognized in a similar manner to today's legacy lease accounting guidance. This ASU could also significantly affect the financial ratios used for external reporting and other purposes, such as debt covenant compliance. This new guidance is effective for the Company beginning in fiscal 2020, with early adoption permitted. In July 20I8, the FASB issued ASU 20I8-11, Leases (Topic 842), Targeted Improvements which provides an additional transition method that allows entities to recognize a cumulative effect adjustment to the opening balance of retained earnings in the period of adoption. The Company is currently in the process of assessing the impact of this ASU on its consolidated financial statements with the intention to adopt this ASU in fiscal year 2020.

Intangibles – Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment. In January 2017, the FASB issued ASU 2017-04 which simplifies the test for goodwill impairment by eliminating Step 2 from the Goodwill impairment test. This new guidance is effective for the Company beginning in fiscal year 2021. The adoption of this standard is not expected to have a material impact on the Company's financial statements.

Management does not believe that any other recently issued but not yet effective accounting standards, if currently adopted, would have a material effect on the accompanying condensed consolidated financial statements.

Results of Operations

Three months ended March 31, 2019, compared to the three months ended March 31, 2018

Net Sales and Revenues

Revenue for the three months ended March 31, 2019, was $189,432 compared to $104,140 for the same three month period in 2018, an increase of $85,292 or 82%. The increase was the result of recognizing 3.6%of the Ferring seven year U.S. exclusive licensing & distribution fee that was recorded in January 2019 upon the execution of the agreement between the two companies.

Gross Margin

The gross margin reported for the first quarter ended March 31, 2019 was 94% or $178,454 compared to 86% or $89,716 for the three months ended March 31, 2018. The increase in gross margin was related to the 2019 licensing fee that did not have any cost of sales expenses associated with it. The cost of sales recognized during the first quarter of 2019 were attributed to the small volume of product shipments early in the quarter and the expenses related to the development of the new Ferring packaging and labeling.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the three months ended March 31, 2019 were $527,565 as compared to $229,999 for the three months ended March 31, 2018, an increase of $297,566 or 129%. The increase in SG&A during the first quarter of 2019 compared to the first quarter of 2018 was the result of salaries and benefits being paid to the existing and new staff and additional supporting resources along with higher amortization of director's fees due to the increased stock price in the market. New expenses in 2019 included initial site development work for INVO only centers, increased U.S. and international travel in starting to develop partnerships and business insurances. We also incurred higher legal expenses related to the Ferring agreements and the preparation of the S-1 filing along with higher costs associated with increased investor awareness efforts.

Interest Expense and Financing Fees

During the three month period ended March 31, 2019 we incurred $109,459 in interest expense, an increase of $105,019 compared to $4,440 in the three-month period ended March 31, 2018. The primary reason for the increase in 2019 was the amortization of discount on the 2018 Convertible Notes Payable in the amount of $93,237 along with $13,982 of interest for the same notes. In the first three months of 2019 we had $2,240 of note payable interest compared to note payable interest of $4,440 the first quarter of 2018.

Net Loss

For the reasons stated above, the Company had a net loss of $458,570 for the three months ended March 31, 2019, an increase of $313,847 compared to a net loss of $144,723 for the three months ended March 31, 2018.

Liquidity and Capital Resources

Net cash as of March 31, 2019, was $3,057,466, or $2,845,233 higher than net cash of $212,243 at December 31, 2018.

The Company believes that its cash on hand is adequate to meet the Company's current liquidity requirements for at least the next fifteen months.

Net cash generated by operating activities was $3,088,088 for the three months ended March 31, 2019, compared to net cash used by operating activities of $37,353 for the three months ended March 31, 2018. The increase in net cash was primarily due to the $4,821,428 increase in deferred revenue as a result of the initial exclusive license and distribution agreement fee received by the Company in January 2019 upon the signing of the agreements. Adding to this increase were the decreases in accounts receivable of $151,182 and prepaid expenses of $22,758 and increase in accounts payable and accrued expenses of $20,249. These increases were offset by reductions in accrued compensation of $1,582,595 along with an increase in inventory of $8,172 as we purchased new packaging per the Ferring Agreement. In addition we increased spending on strategic initiatives as outlined in Selling, General and Administrative Expenses above.

The Company started developing and purchasing molds for the next generation of the INVOcell using $48,400 during the first three months of 2019. No cash was used during the first three months of 2018 in investing activities.

Cash used in financing activities was $194,465 during the three months ended March 31, 2019. This was used to pay off principle note payments for both related and non-related party loans during the period.

Our registered independent certified public accountants have stated in their report dated April 16, 2019, filed with the Company's Annual Report on Form 10-K that the Company has a generated negative cash outflows from operating activities, experienced recurring net operating losses, and is dependent on securing additional equity and debt financing to support its business efforts. These factors among others may raise substantial doubt about our ability to continue as a going concern.

Our existing cash resources, and cash flow from operations will provide adequate resources to fully support our operations during fiscal 2019 and beyond. The payment under the Distribution Agreement in this first quarter of 2019 provided us with the strategic funding necessary to execute our business plan over the next 12 to 24 months.

Comparison of the years ended December 31, 2018 and 2017

Net Sales and Revenues

Net sales and revenues for year ended December 31, 2018 were approximately $494,000, compared to approximately $282,000 for the same twelve month period ended December 31, 2017. We believe this improvement is the result of the INVO Bioscience team continually reaching out to doctors to introduce them to the INVO Procedure. These revenues include the shipment of lower introductory price products as we have started to penetrate the U.S. Assisted Reproductive Technology (ART) market. We anticipate we will continue to offer training promotions as we continue to reach out to new international doctors and embryologists so they may see the benefits of INVO's new and disruptive technology. The process of bringing a new facility up and running takes about 6-9 months before we start to see an initial ordering pattern. In both 2018 and 2017 we trained 15 doctors and their embryologists that support them on the unique differences of the INVO Procedure. More than half of these practices are still working through how to properly integrate and recruit patients for the INVO offering. The others have worked through the initial phases and are now reaching new patients they never would have been able to assist before and seeing positive results.

Cost of goods sold for the twelve months ended December 31, 2018 were $90,000 or approximately 18% of revenues compared to $52,000 or the same cost percentage at 18% of revenues for the year ended December 31, 2017. We are taking steps to continually lower our costs and improve our gross margin while delivering high quality products for a fair price.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $3,038,000 in fiscal 2018 an increase of $2,167,000 for the year ended December 31, 2018 compared to the year ended December 31, 2017 from $871,000. This was the result of the issuance of 5,984,000 shares of restricted common stock, a non-cash expense to the board of directors, employees, and consultants/service providers. During 2018 INVO Bioscience continued what it had started in 2016 to market the INVOcell and INVO Procedure across the United States. We continually update our website and issue press releases when key events occur. We have been able to market and demonstrate the INVOcell for the past few years at the Annual American Society Reproductive Medicine (ASRM) Congress held in Denver, CO, San Antonio, TX, and Salt Lake City, UT. The product and the Company were very well received and had hundreds of visitors and interest during the three days of the Congresses. As in all the years past, the Company kept tight control over spending and only purchased the required basic services.

Research and Development Expenses

The Company did not fund any research and development ("R&D") efforts in 2018 or 2017 as a result of its limited funds. Its limited resources were devoted to basic corporate expenses and training new distributors and physicians. We anticipate an increase in R&D spending in the future as we have a number of product improvement ideas and would like to expand our patents.

Interest Expense, Financing Fees and Loss on Settlement of Debt

Interest expense and financing fees increased to approximately $442,000 for the year ended December 31, 2018 compared to approximately $62,000 for the same period in 2017. This increase was the related to the issuance of the 2018 Convertible Notes, including the interest earned on the notes, the quarterly amortization of the note discount and the conversion of three of the notes into common stock during the fourth quarter. The 2017 expense was related to a majority of the 2009 note holders converting their notes into restricted shares of common stock. See Notes 6 and 8 in the consolidated financial statements included herein. This 2017 note conversions also caused a loss on the settlement of that debt in the amount of $41,000 in 2017.

Income Taxes

The Company had aggregate unused net operating losses at December 31, 2018 and 2017, of approximate $21,708,000 and $18,645,000, respectively, which expire at various times through 2038 and are subject to limitations of Section 382 of the Internal Revenue Code of 1986, as amended. The deferred tax asset related to the net operating loss carry forward was approximately $4,124,000 and $3,730,000 at December 31, 2018 and 2017, respectively.

The Company has provided valuation reserves against the full amount of the net operating loss benefit, since in the opinion of management based upon the earning history of the Company, it is more likely than not that the benefits will not be realized.

Net Loss

The net loss for the twelve months ended December 31, 2018 was approximately $3,076,000 as compared to a net loss of approximately $702,000 for the same twelve month period in 2017. The primary reason for the decrease in net loss was the result of the 2018 issuance of 5,984,000 shares of restricted common stock, a non-cash expense to the board of directors, employees and consultants for their services in 2018 as well as earlier years. In addition there was an a $421,000 non cash increase in the interest and financing expenses as a result of the 2018 Convertible Notes issuance and conversion of some of those notes.

Liquidity and Capital Resources

Prior to receiving the $5,000,000 licensing fee in January 2019 as a result of the Ferring transaction our lack of financial resources was the Company's major challenge.

As of December 31, 2018, we had approximately $212,000 in cash compared to approximately $26,000 at December 31, 2017. Net cash used by operating activities in 2018 was approximately $653,000, as compared to net cash used by operating activities of approximately $181,000 for 2017. The increase in net cash used was due to increasing our funds available in 2018 after our private placement of convertible notes was completed in May, which raised approximately $1 million. During 2018 we partially compensated employees and consultants for their services, pay down existing obligations and work on the next generation of the INVOCell. In 2017 funds were used for patent protection, legal fees, training SEC compliance and basic office support (such as rent, telephone and the website). Since early 2009, all current employees and directors have continued to assist INVO Bioscience in its funding requirements by deferring their compensation.

In 2018, INVO Bioscience invested $19,400 in a new mold to produce its own retention device to allow us to offer a lower cost alternative to our customers. Currently we are procuring the basic FDA cleared retention device from a noted and reputable third party and then having it customized to our specifications at a local ISO 13485 Certified and FDA inspected facility. No cash was used from 2017 in investing activities.

During 2018, $859,000 cash was provided by financing activities The Company raised $895,000 from the issuance of the 2018 Convertible Notes and $77,000 from the issuance of restricted shares as part of our private placement in January 2018. Offsetting this was $113,000 of payments made on related party notes. During 2017, $55,000 cash was provided by financing activities. One shareholder purchased $45,000 of restricted shares of common stock and the other shareholder purchased $10,000 of restricted shares of common stock.

Our registered independent certified public accountants have stated in their report dated April 16, 2019, that we have generated negative cash outflows from operating activities, experienced recurring net operating losses, and are dependent on securing additional equity and debt financing to support our business efforts. As reflected in their audit report, our registered independent certified public accountants indicated that these factors, among others, raise substantial doubt about our ability to continue as a going concern.

Our registered independent certified public accountants have stated in their report dated April 16, 2019, that we have generated negative cash outflows from operating activities, experienced recurring net operating losses, and are dependent on securing additional equity and debt financing to support our business efforts. As reflected in their audit report, our registered independent certified public accountants indicated that these factors, among others, raise substantial doubt about our ability to continue as a going concern

Our existing cash resources, cash flow from operations will not provide adequate resources for supporting operations during fiscal 2019. As announced we entered into a Distribution & Supply Agreement with Ferring International Center S.A. in the fourth quarter of 2018 to market, promote, distribute and sell our products within the United States. We completed this arrangement on January 14, 2019 and as part of the closing process the Company received a $5 million one-time license payment. We believe this along with our anticipated sales from the agreement as well as other revenues will provide the Company with cash resources it needs for the next 12-24 months. We will be utilizing some of this funding to pay down existing liabilities and a portion of our accrued compensation balance. We may continue to seek alternative funding to execute our longer term business plan. Although there can be no assurance that an additional source of funding will materialize, we currently believe that we will be able to obtain the funding we need to continue to expand our business. However, if we do not raise additional capital in the near future we may have to curtail our spending.

Off-Balance Sheet Arrangements

Under SEC regulations, we are required to disclose our off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, such as changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that are material to investors. An off-balance sheet arrangement means a transaction, agreement or contractual arrangement to which any entity that is not consolidated with us is a party, under which we have:

- Any obligation under certain guarantee contracts;
- Any retained or contingent interest in assets transferred to an unconsolidated entity or similar arrangement that serves as credit, liquidity or market risk support to that entity for such assets;
- Any obligation under a contract that would be accounted for as a derivative instrument, except that it is both indexed to our stock and classified in stockholder's equity in our statement of financial position; and
- Any obligation arising out of a material variable interest held by us in an unconsolidated entity that provides financing, liquidity, market risk or credit risk support to us, or engages in leasing, hedging or research and development services with us.

We do not have any off-balance sheet arrangements that we are required to disclose pursuant to these regulations. In the ordinary course of business, we enter into operating lease commitments, purchase commitments and other contractual obligations. These transactions are recognized in our financial statements in accordance with generally accepted accounting principles in the United States.

Inflation

We believe that inflation has not had a material effect on our operations to date.

BUSINESS

COMPANY BACKGROUND

INVO Bioscience was formed in January 2007 under the laws of the Commonwealth of Massachusetts under the name "Bio X Cell, Inc.," which was the business successor to Medelle Corporation ("Medelle"). Dr. Claude Ranoux was the founder and vice president of Medelle and Kathleen Karloff was a vice president of Medelle. Between 2001 and 2006, Medelle raised $8 million in venture capital, which was used to develop and validate a device called the "INVOcell." Medelle conducted pre-clinical safety testing and performed a human efficacy clinical study. Due to a delay in obtaining U.S. Food and Drug Administration ("FDA") clearance for the INVOcell, venture capital investments ceased and, by the end of 2006, Medelle ceased operations. Medelle assigned all of its assets to a trustee who liquidated those assets and distributed the proceeds to creditors. In that process, Dr. Ranoux purchased all of the assets of Medelle for $20,000 and contributed those assets to Bio X Cell, Inc. upon its formation in January 2007, including four patents related to the INVOcell technology.

On December 5, 2008, Bio X Cell, Inc., doing business as INVO Bioscience, and each of the shareholders of INVO Bioscience (the "INVO Bioscience Shareholders") entered into a share exchange agreement (the "Share Exchange Agreement") and consummated a share exchange (the "Share Exchange") with our predecessor Emy's Salsa Aji Distribution Company, Inc. ("Emy's"). Upon the closing of the Share Exchange on December 5, 2008 (the "Closing"), the INVO Bioscience Shareholders transferred all of their shares of common stock in INVO Bioscience to Emy's. In exchange, Emy's issued to the INVO Bioscience Shareholders an aggregate of 38,307,500 shares of Emy's common stock, representing 71.9% of the shares issued and outstanding immediately after the Closing. As a result of the Share Exchange, INVO Bioscience became a wholly-owned subsidiary of Emy's. After the Closing, the Company had 53,245,000 shares of common stock outstanding.

At Closing, Emy's officers and directors resigned from their positions. Kathleen Karloff was appointed as Chief Executive Officer, Secretary and Director and Dr. Claude Ranoux was appointed as President, Treasurer and Director.

Immediately following the Closing, the Company entered into a securities purchase agreement (the "Securities Purchase Agreement") with GRQ Consulting, LLC and Whalehaven Capital Fund Limited. Pursuant to the Securities Purchase Agreement, the investors invested $375,000 in exchange for 375,000 shares of our common stock at a price of $1.00 per share, subject to anti-dilution protection. After the Closing, the Company had 53,245,000 shares of common stock outstanding.

COMPANY OVERVIEW

We have recently begun to commercialize our proven and patented technology that we believe will revolutionize the treatment of infertility. Our device, the INVOcell, and the INVO Procedure are designed to provide an alternative infertility treatment for the patient and the clinician; it is less expensive and simpler to perform than current infertility treatments. The simplicity of the INVO Procedure relates to the ability to potentially perform the infertility procedure in a physician's practice rather than in a specialized facility at a much lower cost overall than current infertility treatments, including in vitro fertilization ("IVF"). Therefore, we believe that the INVO Procedure has the ability to be made available in more locations than conventional IVF, especially outside the United States. INVO also allows conception and embryo development to take place inside the woman's body; an attractive feature for most couples.

In May 2008, we received notice that the INVOcell product meets all the essential requirements of the relevant European Directive(s), and received CE Marking. The CE marking (also known as CE mark) is a mandatory conformity mark on many products placed on the single market in the European Economic Area (EEA). The CE marking (an acronym for the French "Conformité Européenne") certifies that a product has met EU health, safety and environmental requirements, which ensure consumer safety. We are currently awaiting the approval of our CE Mark re-certification and .expect to obtain regulatory authority to distribute product in the European Economic Area, provided we comply with local registration requirements as discussed herein (*i.e.,* the European Union, Australia, New Zealand, Africa and most parts of the Middle East and South America).

THE INVOCELL TECHNOLOGY

Our product, the INVOcell medical device, is designed to treat infertility at a lower cost than other treatments available in today's marketplace, including IVF. The INVOcell technology is a fertility treatment where mild ovarian stimulation is used. Using a mild stimulation protocol, 1-7 follicles are retrieved from a woman in a physician's office with the patient under light sedation with or with local anesthesia. The follicle retrieval is performed using a vaginal probe under ultrasound guidance. Eggs are identified immediately after retrieval in the follicular fluid. During the INVO Procedure, fertilization and embryo development occurs inside the woman's vaginal cavity in a disposable single use device -- the INVOcell -- that holds the eggs, sperm and culture medium, a nutrient liquid.

Sperm collection and preparation generally occur before egg retrieval. Culture medium (~1ml) is placed in the inner vessel of the INVOcell. Eggs and a low concentration of motile sperm are placed into the medium and the inner vessel is closed and secured in the protective outer vessel. The INVOcell is placed in the patient's vaginal cavity for an incubation period of three (3) days in the United States and five (5) days in other countries. A retention system can be used to maintain the INVOcell system in the vagina during the incubation period. The retention system consists of a diaphragm type device with holes in the membrane to allow natural elimination of vaginal secretions. The INVOcell is designed so that no vaginal fluids penetrate the outer vessel thus ensuring that the inner vessel is not contaminated while allowing the necessary CO2 for fertilization to pass through. The eggs, sperm and media are inserted into the INVOcell and then the INVOcell is placed in the vaginal cavity, this process takes approximately 30 minutes.

After three (3) to five (5) days the patient returns to the physician's office where the retention system and the INVOcell are removed. The protective outer vessel is discarded and the inner vessel is placed in a warming test tube block. The contents of the device are then aspirated and placed into a petri plate whereas the embryologist can evaluate the best embryo(s) for transfer. A trained clinician can readily identify the best embryos for transfer. The embryos to be transferred are aspirated into a standard transfer catheter for transfer into the patient's uterus. This second process is estimated to take approximately 20-30 minutes. All INVO related medical procedures can be performed in a physician's office furnished with the necessary equipment thereby avoiding the requirements of an IVF facility and the associated costs to build and maintain such a facility.

SUMMARY OF OPERATIONS

INVO Bioscience operates by outsourcing many key operational functions in the development and manufacturing of the INVOcell device to keep fixed costs to a minimum. Our most critical management and leadership functions are carried out by our core management team. We have contracted out the manufacturing, packaging/labeling and sterilization of the device, respectively, to a certified manufacturer to mold the parts, to a medical manufacturing company to assemble packages and label the product and to a sterilization specialist to perform the gamma sterilization process. Outsourcing such operations as described, expedites production and eliminates the need for in-house capital equipment expenditures.

To date, we have completed a series of important steps in the development and manufacturing of the INVOcell:

- Manufacturing: Our parts and manufacturing processes have been validated. Our facilities and Quality Management Systems (QMS) have been inspected twice by the FDA and have received positive reports. Manufacturing of inventory is ongoing. As of December 31, 2018, we had approximately 100 INVOcell devices ready for sale, and approximately 3,600 devices molded and ready for assembly, sterilization and packaging. Our suppliers provide us with virtually an unlimited capability, with all manufacturing done in New England.
- All raw materials utilized for the INVOcell are medical grade and commonly used in medical devices (i.e.; medical grade silicone, medical grade plastic). Our principal mold supplier is a well-established company in the molding industry and is ISO 9001 Certified. Our contract manufacturer for the INVOcell is ISO 13485 Certified and FDA inspected.
- CE Mark: INVO Bioscience is in the process of re-certifying the CE Mark. The CE Mark permits the sale of devices in Europe, Australia and other countries that recognize the CE Mark, subject to local registration requirements.
- Clinical Trials & FDA Registration: Safety and efficacy of the INVOcell device has been demonstrated and cleared for marketing and use by the U.S. FDA. INVO Bioscience has received ISO 13485, MDD/CMDCAS registration which is effective through 2018.

- Support of Practitioners: Clinicians and laboratory directors have used the INVO method and the feedback has been positive; practitioners appreciate the INVO method is a patient-friendly procedure, which is easy to perform and effective.
- Marketing Trials/Studies: A number of fertility clinics completed clinical studies in Colombia, Peru, Bolivia and Brazil, South America, showing efficacy rates in the 33%-43% range. A U.S. clinical study utilizing the INVOcell and procedure was completed in 2014 and yielded a clinical pregnancy rate of 60% and a live birth rate of 55%. A practice currently offering the INVO Procedure is experiencing a 65% pregnancy rate. Current U.S. physicians treating patients with the INVO Procedure are reporting pregnancy result minimally equivalent to IVF.

CURRENT MARKET OPPORTUNITY

According to the *European Society for Human Reproduction* ("ESHRE") in 2018, Assisted Reproductive Technologies ("ART") Fact Sheet, there were more than 150 million infertile couples in the world. While there have been large increases in the use of IVF, only 1.5 million ART cycles are now performed globally each year, producing around 350,000 babies. This amounts to the treatment of approximately 3% of the infertile couples worldwide being treated and only 1% having a child though IVF. A survey by "*Resolve: The National Infertility Association*," indicates the two primary reasons couples do not use IVF is cost and geographical availability. We can provide a locally available treatment option that can be performed in a facility without the majority of the expensive equipment required for IVF, and at less than half of the cost of IVF, helping millions of infertile couples throughout the world where IVF is not currently available or is too costly.

IVF is an effective treatment option for many infertile couples. Our patented and proven INVO technology is a unique, low cost fertility treatment that is much simpler to perform than IVF. The procedure can be provided without an IVF center and therefore can be made available in more locations than IVF. We believe we are well positioned to capture a significant share of this unmet market. With our INVOcell device and technique, fertilization and early embryo development happens within the vaginal cavity rather than an incubator. Oocytes and sperm are fertilized and developed into embryos within the INVO device while contained by the woman's vaginal cavity.

According to ESHRE (2014), approximately 1% of infertile couples have a child by an infertility treatment, including IVF, intra uterine insemination ("IUI") and other fertility treatments, representing a $6.6 billion annual worldwide market. This leaves most of the infertile couples untreated with an estimated unmet market opportunity in the billions. INVO Bioscience believes a portion of this market will be met by the INVOcell device. Much of the unmet market is located in developing countries where many patients cannot afford, and have limited access to, IVF. We believe that developing countries offer a large and ready market for the INVO Procedure.

In the United States infertility according to the American Society of Reproductive Medicine (ASRM) (2017) affects an estimated 10%-15% of the couples of child bearing age. Based on preliminary 2015 data from CDC's National ART Surveillance System, 231,936 IVF cycles were performed at 464 IVF centers with 186,157 cycles going through transferring the embryo and 45,779 cycles being frozen for future use. These transferred cycles resulted in 60,778 live births and 72,913 babies born yielding an approximate 33% overall pregnancy rate. Although the use of IVF is still relatively rare as compared to infertility demand, its use has doubled over the past decade. Today approximately 1.6% of the infants born in the United States every year are conceived through IVF.

In November 2015, we received notice that the INVOcell device met all of the requirements for U.S. FDA clearance. The FDA clearance has allowed the company to begin launching the INVOcell product and procedure in the United States. We anticipate that this will be our primary focus over the coming years.

As indicated above, in May 2008 we received notice that the INVOcell device met all of the essential requirements of the relevant European Directive, and received CE marking. The CE marking certifies that a product has met European health, safety and environmental requirements, which ensure consumer safety. Manufacturers in Europe and abroad must meet CE marking requirements where applicable in order to market their products in Europe. Since it has been over nine years since we first received the CE marking, we are currently in the re-certification process with the appropriate regulatory bodies and expect to have this completed in the near future. With CE marking, we will have the necessary regulatory authority to distribute our INVOcell device in the European Economic Area, subject to local registration regulations.

Currently, we are continuing to establish agreements with distributors and train physicians outside of the U.S. including Asia, South America, Central America, Europe, the Middle East, India and Africa. The international market will be secondary to the U.S. market for the Company since we believe the revenues from these secondary markets will not be as profitable as the U.S. market. Upon receiving additional funding, as to which there is no guaranty, the company's ability to expand in the international market will be increased.

COMPETITION

The infertility industry is highly competitive and characterized by technological improvements. New ART services, devices and techniques may be developed that may render the INVOcell obsolete. Competition in the areas of infertility and ART services is largely based on pregnancy rates and other patient outcomes. Accordingly, the ability of our business to compete is largely dependent on our ability to achieve adequate pregnancy rates and patient satisfaction levels. The INVO Procedure will offer an alternative treatment to couples that currently do not have access to treatments because of cost or location. Infertility clinics can expand their businesses by offering INVO in satellite centers that can be opened at a substantially lower cost than an IVF center. We are not aware of any direct competitors to INVO Bioscience or the INVO Procedure using the INVOcell device. However, there are existing infertility treatment regimes that the INVOcell will compete with when an infertile couple, in conjunction with their physician, is choosing the treatment method for their infertility. We believe that the menu of currently available clinical infertility treatment methods generally is limited to IUI and IVF.

Competing Treatments

Intra Uterine Insemination (IUI): In IUI treatments, ovarian stimulation protocols with induction of ovulation are frequently used to recruit several follicles and improve clinical pregnancy rates. When monitoring of ovulation indicates that the female patient is ready to ovulate, the male patient will produce a sperm sample in the fertility doctor's office. The sperm is then prepared and delivered to the uterus through a catheter. Currently IUI can only treat approximately 40% of the causes of infertility. For example, IUI does not address infertility causes such as tubal disease and other conditions that are treatable by IVF and the INVOcell device and process. In addition, IUI does not produce the diagnostic information such as fertilization that an IVF or INVO cycle produces. Approximately 600,000 IUI cycles are performed annually by a subset of about 5,000 doctors in the U.S. as well as by IVF providers. In Europe, at least 550,000 IUI cycles are performed annually. The cost of a single IUI treatment can range from $800 to $3,000 per cycle in the U.S. and $500 to $2,000 in Europe. The intra-country differences in cost primarily depend on the stimulation protocol and the ovulation monitoring used by the physician.

In Vitro Fertilization (IVF): IVF addresses tubal factor, ovulatory dysfunction, diminished ovarian reserve, endometriosis, uterine factor, male factor, unexplained infertility and other causes. IVF bypasses the function of the fallopian tube by achieving fertilization within a laboratory environment. Ovarian hyper-stimulation is common with IVF treatments to recruit numerous follicles to purportedly increase the chances for success. Follicles are retrieved trans-vaginally using a vaginal probe and ultrasound guidance. General anesthesia is frequently used due to the number of follicles retrieved and the resulting discomfort experienced by the patient. The eggs are identified in the follicular fluid and combined with sperm and culture medium in culture dishes, which are placed in an incubator with a temperature and gas environment designed to mimic the condition of the fallopian tubes. Once the embryos develop, typically over a 3-5 day period, they are transferred to the uterine cavity. In 2015, according to a report prepared by the U.S. Center for Disease Control ("CDC"), there were 231,936 ART cycles. Out of these cycles 45,779 were performed for freezing of embryos for the future and 186,157 cycles were performed through embryo transfer. These cycles resulted in a clinical pregnancy rate of 38.6%. (CDC 2015 ART Report). The INVO Procedure will be offered at approximately $6,500 per cycle with a pregnancy rate comparable to traditional IVF. According to Resolve, National Fertility Association, IUI cycles costs $275- $2,457 per cycle (variability due to drug costs and diagnostics inclusion on some cycles) and the cost range of IVF is $9,000-11,000 per cycle plus drug costs. Drug cost range from $3,000-$5,000 per cycle brining the cost range of IVF to $12,000 - $16,000 per cycle. The INVO Procedure is being offered at $6,000-$8000 per cycle inclusive of medications thereby making it much more affordable than traditional IVF.

The cost to the patient for a single IVF cycle (including drugs) is in the $11,000 - $16,000 range in the U.S. and can go as high as $20,000 depending on the IVF center and the services required by a patient. The cost of drugs for an IVF cycle ranges from $2,500 to $4,000. The average cost per live birth using IVF can exceed $50,000 since the successful patient may require more than one cycle depending on the age of the patient. Many patients who would be good candidates for IVF are unable to access it because of the high cost and lack of insurance reimbursement. Additional obstacles to IVF often include significant distances to IVF clinics; travel costs; and time off from work. In addition, some couples experience concerns regarding IVF such as the possibility of laboratory errors resulting in receiving another person's embryo.

Competitors

We operate in a highly competitive industry, which is subject to competitive pricing and rapid technological change. The first IVF baby, Louise Brown was born in 1977, making the IVF treatment 40 years old. Our INVOcell device is the first new treatment option for patients in 40 years. The market for fertility treatment and devices are highly competitive in terms of pricing, functionality and service quality, the timing of development and introduction of new products and services and terms of financing. We face competition from all ART practitioners and device manufacturers. Our competitors may implement new technologies before we do, allowing them to offer more attractively priced or enhanced products, services or solutions. Our competitors may have greater resources in certain business segments or geographic markets than we have. We may also encounter increased competition from new market entrants or alternative ART technologies. Our ability to compete in this market successfully will require us to adapt to economic or regulatory changes, to introduce new products to the market and to enhance the functionality while reducing the cost of new and existing products.

Our principal ART medical-device competitor is Anecova, a Swiss life sciences company with an intrauterine device under development for infertility treatment. This device is a very small silicone tube with 360 micro perforations. Oocytes are fertilized outside the device and then placed in the tube, which is placed inside the woman's uterus for early embryo development. After 1-5 days, the device is removed and the best embryo(s) are transferred back into the woman's uterus. We believe that the device is more difficult to use than the INVOcell due to its size and the requirement to place the device in the uterus, a sterile environment. We expect that the precision manufacturing of the Anecova device will drive its cost close to $1,500, which is higher than our cost of manufacturing. The Anecova device would only be available in hospitals and IVF Centers at a significantly higher cost than the INVOcell. Currently the Anecova device has not begun clinical studies in the United States that will be required for FDA approval, therefore the device will not be available for some time in the United States and many other areas of the world.

Competitive Advantages

We believe that the INVOcell has the following competitive advantages:

Lower cost than IVF with similar efficacy: The INVOcell is substantially less expensive than IVF due to a lower cost of supplies, labor, capital equipment and overhead. We estimate that an IVF center requires at least $500,000 of laboratory capital equipment as well as highly trained personnel. In contrast, the cost of laboratory capital equipment to set-up an INVOcell procedure is approximately $100,000 and does not require highly trained embryologists that are required for traditional IVF. .

In 2016, according to a draft report prepared by the U.S. Center for Disease Control ("CDC"), there were 263,577 ART cycles. Out of these cycles 65,840 were performed for freezing of embryos for the future and 197,000 cycles were performed through embryo transfer. These cycles resulted in 31%live births with a clinical pregnancy rate of 35.9%. (CDC 2016 ART Report). The INVO procedure will be offered at approximately $6,500 per cycle with a pregnancy rate comparable to traditional IVF. According to Resolve, National Fertility Association, IUI cycles costs $275- $2,457 per cycle (variability due to drug costs and diagnostics inclusion on some cycles) and the cost range of IVF is $9,000-11,000 per cycle plus drug costs. Drug cost range from $3,000-$5,000 per cycle brining the cost range of IVF to $12,000 - $16,000 per cycle. The INVO procedure is being offered at $6,500 per cycle inclusive of medications thereby making it much more affordable than traditional IVF.

Similar cost than IUI with greater efficacy: It is estimated by Resolve that in the U.S. currently IUI averages $1,500 per cycle with approximately <10-12% pregnancy rate while IVF averages $12,000 - $16,000 range per cycle with an average of 35.9% pregnancy rate. With INVO, we believe that the Ob/Gyn and reproductive endocrinologists will benefit by providing a superior product than IUI with good financial margins, efficacy rates more than triple IUI while treating the full range of infertility indications. In Europe, according to ESHRE the average cost per pregnancy using IUI is $12,000. According to ESHRE the average cost per pregnancy for IVF is $21,354 while for INVO it is only $13,888: a savings of more than $7,000 per pregnancy. Using INVO could reduce annual infertility costs in Europe by more than $650 million.

Greater geographic availability: According to 2016 CDC Report, there are approximately 463 IVF centers in the U.S. In addition, by having INVO geographically available in Ob/Gyn offices, couples will avoid the travel costs and absence from work associated with long-distance IVF treatments. The medical staff at these centers could easily learn the INVO technique and offer it as a lower cost treatment option for their patients through satellite centers. According to the American College of Gynecologists (ACOG) there are also approximately 5,000 Ob/Gyn physicians in the U.S. who offer infertility services such as the IUI treatment but lack the facilities to offer an IVF treatment. Since INVO does not require a specialized lab facility, large costly equipment or highly specialized staff, the INVO treatment may be offered in a doctors' office with the addition of minor capital equipment potentially expanding business for these physicians. Therefore, in the U.S. alone, INVO could be 10 times more available than conventional IVF. Ob/Gyn offices worldwide could offer INVO as an alternative or follow up treatment to IUI and generate a significant new revenue stream.

Greater patient involvement: With INVO, the patient uses her own body as the incubation environment. This creates a greater sense of involvement, comfort and participation for patients who know that the fertilization is happening within their own bodies. In some cases, this may free a couple from ethical or religious concerns, or fears of laboratory mix-ups that could result in a patient receiving another couple's embryo(s).

SALES AND MARKETING

Customers

Currently our customers are the doctors who have the ability to offer the INVO Procedure to their patients. Currently, we have trained doctors from 22 states. Our goal is to make our treatment easily accessible by have at least one location in every state. We typically train both a reproductive endocrinologist and an embryologist from the practice. Participating doctors will likely have to make medical and business adjustments as they introduce the INVOcell device and procedure to others within their offices and to prospective patients as they determine where INVO fits into their practice. Without destroying their current business model, doctors will work to adjust their practices to allow for the integration of the INVO Procedure.

Every center offering the INVO Procedure today is in its own stage of the integration process. Some centers have completely integrated the INVO Procedure into its product offerings, while others are at the beginning stages of patient recruitment. A couple centers are planning to expand to new offices offering the INVOcell to help meet the demand. Additionally, we are beginning to see once one practice begins to offer the INVO Procedure other physicians within the general area have reached out to us to become trained in the INVO method.

Since receiving FDA clearance we have shipped over 3,800 INVOcells to doctors in the U.S., both revenue and non-revenue producing, in addition to 500 INVOcells internationally.

Product Pricing

For the various markets, we price the INVOcell Intravaginal Culture System technology based on discussions with our advisory board of physicians and potential strategic partners, and reflect the innovative features of the device, the savings in physician's laboratory fixed costs and the billings the physician will receive from patients to perform INVO. Our goal is to have the INVO procedure offered to infertile couples as a lower cost alternative with comparable success rates to IVF.

INVOcell Culture Device: For the U.S. market our price for the INVOcell and retention devices has been agreed to with Ferring. Ferring has minimum quantities that they must buy from the company on an annual basis in order to their exclusivity. In the international markets the price will be determined as we enter them based on current offerings and discussions with key partners. IVF centers or Ob/Gyn groups purchasing a large number of devices and promoting the INVO process may receive discounted prices and certain free advertising of their facility on our website. It is expected that the INVOcell will sell for different prices throughout the world as a reflection of different economies and prices of the IVF procedure in different countries.

INVOcell Retention Device: This is a single-use, modified diaphragm that includes holes to allow for natural drainage of vaginal fluids. The current model is an FDA cleared and CE Marked product purchased from a US company. This retention device currently sells for $70 each. In 2018 the Company developed its own single use lower cost product. This retention device specification is equivalent to the current modified diaphragm but will not be available for sale until the completion of testing before being accepted and released by INVO Bioscience for commercial sale. This will significantly reduce the cost of goods moving forward as well as the price to the physicians.

Fixed Laboratory Equipment: The equipment used in the INVO procedure (microscope with video system, bench centrifuge, incubator without CO2, bench warmer and laminar flow hood) is readily available in the market. The complete set up for the INVO procedure currently costs approximately $125,000 in the U.S. and $150,000 if ICSI is included in the lab.

Sales Strategy

As of December 31, 2018, sales and marketing activities are being performed by the Company's CEO and VP of Global Operations. We anticipate building an international sales team in 2019 and beyond, staring with the addition of Michael Campbell as our Chief Operating Officer and VP of Business Development who joined the Company in February 2019. Mr. Campbell was most recently the Vice President of IVF Americas Business Unit for Cooper Surgical, Inc. (CSI), a wholly owned subsidiary of The Cooper Companies (NYSE: COO), and is also a member of the board of directors for INVO Bioscience. Mr. Campbell has substantial medical device sales, marketing and business development leadership experience within Global Fortune 500 and Start-up Company environments. During his over 12-year career at Cooper Surgical, he has been responsible for IVF product portfolio sales globally including the US, Canada, Latin America, Europe, Middle East, Africa, and Asia Pacific regions. Our sales efforts include the following three approaches:

Domestic - In the United States our sales will come from our relationship with Ferring Pharmaceuticals - The Company will initially ship bulk shipments to Ferring on a quarterly basis per volumes in the Supply Agreement and will adjust as needed to allow for the timely delivery of INVOcells to the physicians. Ferring's strategy is to market to Reproductive Endocrinologist's (REI's) and OB/GYN's to offer INVO in place of Inter-Uterine Insemination (IUI) since the overall expense for an actual pregnancy is less for INVO, as multiple cycles of IUI are typically required and still produce a very low pregnancy rate as compared to INVO.

Distributor Partnerships-- In foreign countries, we have and will continue to establish local partnerships to access the countries' markets. With the distributor-to-physician model, the distributors will be selling to IVF centers, medical practices and physicians directly. We will support the distributors' efforts with training, both to the distributors' trainers as well as to the physicians directly. We will be expanding our international sales & marketing presence in 2019.

Partnering with Doctors in opening centers that offer INVO as the primary reproductive service – We are looking to work with current doctors in areas of the US where there is demand but currently no IVF facilities. This approach may take many different forms all of which we are willing to explore. The Company plans to build five (5) centers in the United States in the coming years.

Target Markets

The breadth and depth of our expansion in 2018 will be subject to the amount of additional capital we are able raise. We expect to continue to launch the sale of the INVOcell Culture System in the United States, Canada, Asia, South & Central America and India.

Worldwide – According to ESHRE February 2018, one in six couples worldwide experience some form of infertility problem at least once during their reproductive lifetime. The current prevalence of infertility lasting for at least 12 months is estimated to be around 10% worldwide for women aged 20-44. In 2014, the latest year for which figures are available, almost 800,000 treatment cycles were reported from 39 European countries. The global need for ART is estimated to be at least 1,500 cycles/million population per year. With the global population of 7.5 billion, the estimate for infertility prevalence is 50 million couples.

U.S. -- According to The National Survey of Family Growth from the Centers for Disease Control, in the year 2016, Over 7.5 million women in the U.S. had difficulty conceiving (12.4%) With only about 760,000 couples receiving fertility treatment (IUI, IVF and other treatments). This leaves more than six million couples receiving no treatment at all for their infertility. According to the ASRM's 2015 Access to Care Summit White Paper, the largest barrier to patients seeking treatment is the cost of the treatment and the lack of insurance coverage for the cost. We are currently offering the INVO procedure in the U.S. at $6,500 dollars per cycle inclusive of medications. Our goal is to penetrate 5% of the currently untreated infertility market over the next few years, although no assurances can be made that we will achieve our goal in our target markets or at all.

Europe -- ESHRE estimated in 2018 that Europe had approximately 10 million infertile couples, of which about 800,000 were estimated to have received ART treatments. That would leave over 9 million infertile couples untreated.

Preliminary Sales Strategy

Launching INVO in the U.S. market required U.S. FDA DeNovo clearance, which we received in November 2015. Our strategy through 2018 is to focus our resources primarily on U.S. sales in order to make INVO a standard of infertility care throughout the United States. Currently, we are providing the INVO product and training at a low introductory price to doctors who are interested in offering the INVO Procedure at their practice. This approach appears to be successful, as there are currently 89 facilities offering or referring the INVO Procedure. As these doctors are adding our INVOcell device and procedure to their existing services it will take time for the INVO method to gain market traction. This is partially due to a portion of patients who are more comfortable using the more traditional and well-known infertility service approaches. On average, it appears the integration of the INVO method into physician's practices takes approximately 6-9 months. We are taking steps to assist physicians who are having difficulty integrating the INVO method into their established practices.

In January of 2019, INVO Bioscience closed on an exclusive sales and marketing licensing agreement with Ferring Pharmaceuticals for the U.S. market. INVO Bioscience will continue to manufacture product for Ferring and the international market, Ferring will have all rights to sell and market the INVOcell in the U.S..

FDA clearance is required before U.S. products are allowed to be registered in other countries. The FDA approval granted in 2015 will allow the INVOcell to be registered and market in countries such as Mexico, Australia, New Zealand, Hong Kong, Malaysia, China and other countries in Asia.

The CE Mark, which is currently being renewed, allows us to sell our INVO device in Europe and certain countries in South America, the Middle East and Africa, subject to local registration requirements. Our strategy is to focus on the U.S. over the next two years and then shift our focus to our international markets. Over the next two years, we expect to develop additional resources to launch INVO in the developing world. These areas are in need of more affordable fertility treatments due to the economics, high infertility rates of up to 25%, and the relatively low availability of IVF procedures.

Insurance Reimbursement for Infertility Treatment

In the United States, generally there is minimal insurance coverage for infertility treatments, and such insurance coverage varies on a state by state basis. Currently, 15 states mandate some form of insurance reimbursement for infertility treatment (primarily the drug components) and three (3) states mandate reimbursement for IVF, while other states cover some form of infertility treatment, but specifically exclude IVF due to cost. Additionally, certain states have coverage for IUI and not IVF.

Under current fertility service insurance standards, many practices require an infertile patient have at least three cycles o IUI before pursuing IVF. As a result, many patients are often referred to IVF when multiple IUI attempts are not successful. According to Society for Maternal-Fetal Medicine, in 2015 the pregnancy rate for each natural IUI cycle is approximately 4% to 5%, and in the event fertility drugs are used, the pregnancy rate increases to approximately 7% to 16%. Currently, there are no available national statistics on live birth rates. In the future, we estimate third-party insurance payers could save more than $7,000 per pregnancy by requiring the patient to try INVOcell first.

Most European countries have some level of coverage for infertility treatment, but the level of coverage varies from country to country and often varies within countries. For example, the National Health Service in the UK covers 20% of most costs for infertility treatment; however, such standard is not applied universally throughout the UK. In 2010, the Province of Quebec mandated the full payment of up to 3 ART cycles for residents; however, in November of 2016 they program was cancelled.

We believe that the INVOcell process will be treated favorably by as it lowers cost and has a high efficacy rate. According to the data we have found the Company has determined based on the typical number of cycles it take to get pregnant, in the US, the average cost per pregnancy using IUI is $12,000 and IUI is only indicated for approximately 40% of the infertile population. However, the INVOcell device, which based on the 450 clinical cycles submitted to the FDA in 2014 by the Company, has equivalent pregnancy rates as traditional IVF and treats the same indications as IVF therefore is a very effective treatment for a majority of infertile couples.

Branding and Promotion

We have a logo associated with the INVOcell device that is refined for the infertility market. We have trademarked "INVO Bioscience", "INVOCELL" and "INVO". In 2016, we launched our new website providing a more user-friendly interface and more comprehensive FAQ section. We continually make improvements to our website to include special pages for clinicians and patients. Subject to available capital, we plan to include materials that medical professionals and patients can print, including status reports and news items. We expect our website will eventual include training videos for potential customers, both physicians and patients, to provide a visual representation of how INVOcell works.

REGULATION

Domestic Regulations

The manufacture and sale of our products are subject to extensive regulation by numerous governmental authorities, principally by the FDA and corresponding foreign agencies. The FDA administered the Federal Food, Drug and Cosmetic Act and the regulations promulgated there under. We are subject to the standards and procedures with respect to the manufacturing of medical devices and are subject to FDA inspection regarding compliance of such standards and procedures. The FDA classifies medical devices into one of three classes based upon the degree of risk associated with each medical device and the extent of control needed to ensure safety and effectiveness. The INVOcell device and process secured a DeNovo Class II notification clearance in November 2015 allowing us to introduce the device into the U.S. market.

Every company that develops, manufactures or assembles medical devices is required to register with the FDA and adhere to certain "good manufacturing practices" in accordance with the FDA's Quality System Regulation, which regulates the manufacture of medical devices, prescribes record-keeping procedures and provides for the routine inspection of facilities for regulatory compliance. The FDA also has broad regulatory powers in the areas of clinical testing, marketing and advertising of medical devices.

Medical device manufacturers are routinely subject to periodic inspections by the FDA. If the FDA believes a company is not operating in compliance with applicable laws and regulations, the FDA and the Department of Justice can:

- place the company under observation and re-inspect the facilities;
- issue a warning letter apprising of violating conduct;
- detain or seize products;
- mandate a recall;
- seek to enjoin future violations;
- seek civil and criminal penalties against the company, its officers or its employees; and
- issue a form 483 to initiate corrective actions by the company

INVO Bioscience has successfully completed two comprehensive inspections by the FDA, occurring in January 2012 and November 2014, resulting in no action indicated (NAI), meaning all was acceptable to the US FDA. The Company will continue to be the manufacturer of the INVOcell in the US to support Ferring's sales and marketing initiatives. This requires the Company to continue its regulatory responsibilities and compliance activities.

International Regulations

We are also subject to regulations in each of the foreign countries where our products are sold. Many of the regulations applicable to our products in such countries are similar to those of the FDA. Many country's national health or regulatory organizations require our products be qualified before our products are marketed in such country. Many of the countries we are targeting do not have a formal approval process of their own but instead rely on either FDA clearance or the European approval. Some countries require a registration process of listing the INVOcell with the governing body in addition to the United States and European approvals.

Our activities during our development stage have included developing our business plan, seeking regulatory clearance both domestically and internationally, and raising capital

With CE marking, we have had, and when we receive re-certification we anticipate we will have, the necessary regulatory authority to distribute our product after obtaining our registration in the European Economic Area (*i.e.,* Europe, Australia, and New Zealand). In addition, we have the ability to markets in some parts of the Middle East and South America, as they have not implemented medical device regulations. Every country has different requirements; we have completed registrations in some and are in process with others. We continue to work with doctors and distributors submitting additional registrations. Generally, we are registering our product based on the size of the market and our ability to service it given our resources.

In 2009, INVO Bioscience received clearance from Health Canada to market, sell and train on the use of the INVOcell and INVO Procedure in Canada. Although the Canadian government approved the INVOcell, the local physician collages must authorize the use of new products in each Canadian province. These governing colleges also require our product be approved in the U.S. prior to approving it's use in Canada. The INVOcell has been deemed a disruptive technology preventing our partner Invaron Pharmaceuticals from being able to effectively launch product in Canada over the past years. As a result of the approval of the local physician collage and raised funds, in 2016 Effortless IVF, Canada, began to build an center in Calgary Canada of which would only offer INVO services. In August 2017, the center obtained all of its required certifications and began to treat patients. As with most new businesses, the center has been experiencing standard business and operational issues. Effortless IVF, is planning to utilize its experience with the Calgary center to expand and open additional centers across Canada.

In 2012, we received Brazil's National Health Surveillance Agency (ANVISA) clearance approving the sale and use of the INVOcell throughout Brazil. The approval allows INVO Bioscience to enter into one of the largest markets and fastest growing economies in the world with over 190 million people. In 2016, we completed a new registration and added an additional distribution channel, which was later approved by ANVISA in 2017. The Company plans to raise additional funds in order to establish a sales and marketing team to address this opportunity.

In 2012, we selected Sanzyme Ltd. as our partner and distributor for India. Since its section, Sanzyme has been marketing and training doctors throughout the country. In late 2015, they added an embryologist to focus on INVO Procedure training and continue to add additional resources. In 2016, Sanzyme presented at 15 conferences including two international conferences and the IFS world congress. In December 2017, Sanzyme opened a training and use center for doctors and embryologists in Hyderabad. The purpose of the center is to train physicians and allow doctors who do not have the proper facilities to perform procedures. Sanzyme continues to expand its geographical reach across India.

INTELLECTUAL PROPERTY

The Company's success depends in part on our ability to obtain and maintain proprietary protection for our products and technologies. Our goal is to develop a strong intellectual property portfolio that enables us to capitalize on the research and development that we have performed to date and will perform in the future, particularly for each of the products that we commercialize such as the INVOcell. We rely on a combination of patent, copyright, and trademark laws in the United States and other countries to obtain and maintain our intellectual property. We protect our intellectual property by, among other methods, filing patent applications with the U.S. Patent and Trademark Office and its foreign counterparts on inventions that are important to the development of our business.

The Company's product development process has resulted in the development of two (2) active patents covering both the INVOcell device and the INVO Procedure set to expire in July 14, 2024 and April 10, 2020, respectively. The Company is currently in the process of redesigning and completing process improvements on the INVOcell and INVO Procedure for the submission of patent renewals to expand the patents beyond their current expiration dates.

LEGAL PROCEEDINGS

Since 2010, INVO Bioscience, Inc., and one of its directors have been defending litigation brought by investors in an alleged predecessor of INVO Bioscience. On March 24, 2010, INVO Bioscience, Inc. and its corporate affiliate, Bio X Cell, Inc., Claude Ranoux, and Kathleen Karloff were served an Amended Complaint, originally filed on December 31, 2009, by two terminated employees of Medelle Corporation (also named as a co-defendant but no longer active), and a former investor in and creditor of Medelle. Plaintiffs claim that Dr. Ranoux, Ms. Karloff, and Medelle (and INVO Bioscience as an alleged successor corporation) violated alleged duties owed to plaintiffs in connection with the sale or assets of Medelle to Dr. Ranoux. Separate claims were also alleged against INVO Bioscience.

Dr. Ranoux, Ms. Karloff, and INVO Bioscience have challenged these allegations, which they believe are baseless. The assets of Medelle were professionally transferred by an independent third party, after approval by the Medelle Board of Directors representing a majority of its shareholders. Medelle's Board voted to proceed with an assignment for the benefit of creditors (AFBC) and gave complete authority to the President & CEO at that time (neither Dr. Ranoux nor Ms. Karloff) to work with the third-party assignee and to get the best possible price for those assets. The third party was responsible for notifying all the appropriate parties and for filing notices in various professional publications and newspapers of Medelle's intention to sell its assets. The third party also contacted numerous large medical device and bio-pharma companies inquire as to whether they were interested in acquiring the assets. After a private sale was deemed unlikely, the assignee of the assets elected to proceed with a sealed-bid auction of the assets. On the day of the auction, Dr. Ranoux submitted the only bid and was awarded the assets upon full payment.

During 2010, Dr. Ranoux, Ms. Karloff, and INVO Bioscience filed Motions to Dismiss as to all claims, pursuant to M.R.Civ. P. 12(b)(6). In a written decision rendered on November 12, 2010, the judge dismissed all claims against INVO, Bio X Cell, and Ms. Karloff, and also dismissed the claims against Dr. Ranoux alleging civil conspiracy and breach of M.G.L. c. 93A. The judge denied Dr. Ranoux's motion to dismiss the breach of fiduciary duty and fraud claims. The plaintiffs allege in their Amended Complaint that Dr. Ranoux committed fraud by failing to inform them of the details of the Medelle auction.

The survived claims against Dr. Ranoux were submitted to binding arbitration. On February 15, 2013, the mutually-agreed arbitrator ruled in favor of Dr. Ranoux, holding Dr. Ranoux did not withhold information about the auction of Medelle's assets and expressing doubt that the plaintiffs would have invested the resources necessary to make a beneficial use of the assets. The arbitrator's award was then confirmed by the Superior Court on August 21, 2013. The Superior Court's confirmation of the award was affirmed on appeal on October 20, 2013 by the Massachusetts Appeals Court. The Massachusetts Supreme Judicial Court then denied further appellate review.

On October 18, 2016, following motions and argument, the Superior Court issued a memorandum of decision and order denying the plaintiffs' motion for entry of default judgment and assessment of damages against Medelle. Additionally the court allowed entry of final judgment on INVO Bioscience, Bio X Cell, and Ms. Karloff motion of dismissal. On October 27, 2016, the foregoing order was converted to a final judgment dismissing all claims against all defendants.

On November 28, 2016, plaintiffs filed an amended notice of appeal from the Superior Court's decision of October 17, 2016 and the subsequent judgment entered on October 27, 2016. The appeal further challenged the order of dismissal from November, 2010. Plaintiffs did not appeal the claims against Ms. Karloff, as a result the judgment in her favor is now final. The claims against INVO Bioscience, Bio X Cell, Medelle, and Dr. Ranoux are still subject to appeal.

INVO Bioscience and Bio X Cell intend argue vigorously in opposition to the current appeal, consistent with their previous positions that no breach of duty occurred in the sale of Medelle's assets. It is assumed Dr. Ranoux will also oppose the appeal.

Aside from the above-mentioned litigation, neither INVO Bioscience nor Bio X Cell, our wholly-owned subsidiary, either directly or indirectly, are involved in any lawsuit outside the ordinary course of business, the disposition of which would have a material effect upon either our results of operation, financial position, or cash flows.

PROPERTY

We currently do not own any real property, but operate from leased facilities. Our principal executive office located at 407R Mystic Avenue, Suite 34C, Medford, MA 02155 is a month-to-month lease. We moved into this facility in November 2012. This facility is owned by a related-party. See "Certain Relationships and Related Party Transactions." Prior to moving to our current offices, we rented facilities at 100 Cummings Center, Beverly, MA.

EMPLOYEES

As of December 31, 2018, we had two full time employees, Ms. Karloff, Chairperson, Director and CEO; and Lori Kahler, our VP of Global Operations. Mr. Bowdring is a Director, consultant, Treasurer & Secretary, and along with the other Directors assist when needed. Excluding directors and officers, we had no employees from 2010 through 2017.

In February 2019 we hired Mr. Michael Campbell as COO and VP of Business Development, he has been a Director for the past sixteen months. Mr. Campbell has over 20 years in the infertility market most recently with Cooper Surgical as the VP of the IVF America division and previous to this in the position of VP of the international market.

MANAGEMENT

The following table sets forth information with respect to each of our directors, including their current principal occupation or employment and age as of June 3, 2019.

NAME	AGE*	POSITION
Ms. Kathleen Karloff	63	Director and Chief Executive Officer and Secretary, from 2011 through 2015, and from January 1 through September 19, 2016. From September 20, 2016 to date, Ms. Karloff has served as Director, Chairman of the Board, President and Chief Executive Officer.
Dr. Kevin Doody, MD	57	Director from April 7, 2017.
Mr. Robert Bowdring	61	Director from March 2013 through 2015, and from January 1, 2016 to date. From 2011 to March 2013, Mr. Bowdring served as Chief Financial Officer (and principal accounting officer). Further, from September 20, 2016 to date Mr. Bowdring has served as Treasurer and Secretary. Finally, from March 6, 2017 to date Mr. Bowdring has served as Acting Chief Financial Officer (and acting principal accounting officer).
Mr. Michael Campbell	60	Director from October 11, 2017.
Mr. Steven Shum	48	Director from October 11, 2017

* As of December 31, 2018

Kathleen Karloff, Chairperson, Chief Executive Officer and Director

Ms. Karloff co-founded INVO Bioscience in January 2007. Since 2007 Ms. Karloff has served as, and she continues to serve as, a Director of INVO Bioscience. Further, she served as Chief Executive Officer and Secretary from 2008 through September 19, 2016, and since September 20, 2016 has served, and continues to serve, as Chairman of the Board, President and Chief Executive Officer of INVO Bioscience. Since 2007, Kathleen has obtained ISO certification and the CE mark for the INVOcell device and has implemented manufacturing and distribution systems. From 2004 until September 2006, Kathleen was the Vice President of Operations for Medelle Corporation. From 2000 through 2003, Kathleen was the Vice President of Operations for a start-up company Control Delivery Systems developing an intra-ocular drug therapy for Uveitis and Diabetic Macular Edema. The Company was acquired by Psivida LTD. Prior to that, she has held various positions at Boston Scientific during 13 years of dynamic growth from 1983 to 1997 her last position being the Director of Manufacturing. Since leaving Boston Scientific, she has been Vice President of Operations on start-up teams of three device/pharmaceutical companies. Ms. Karloff earned her B.S. in microbiology from Montana State University and attended Northeastern University for MBA coursework.

Kevin Doody, M.D., Medical Director and Director (Effective April 7, 2017)

Dr. Doody serves as Medical Director for INVO Bioscience and is also a member of the Board of Directors. Dr. Doody is a renowned fertility specialist who is the founder and Medical Director for the Center for Assisted Reproduction (CARE Fertility) and Effortless IVF located in Bedford Texas. The Center for Assisted Reproduction, established in 1989, has been a pioneer of assisted reproductive technologies in the north Texas region with several firsts including the first ICSI pregnancy and the first to successfully implement a blastocyst culture system. CARE Fertility had the first pregnancy in the region with a pregnancy following embryo biopsy and pre-implantation genetic testing for cystic fibrosis. CARE Fertility/ Effortless IVF also was the first to adopt the INVOcell™ Intravaginal Culture System since the INVOcell first obtained FDA clearance. Dr. Doody is President of the Society for Assisted Reproductive Technology (SART), on the Board of Directors of the American Society for Reproductive Medicine (ASRM) and a member of the RESOLVE Physician Council. As INVO Bioscience's Medical Director, Dr. Doody provides medical and clinical guidance, INVO education and training, and oversight of risk management and post-market surveillance activities as well as support current and new product development.

Robert J. Bowdring, Director, Secretary, Treasurer and former Chief Financial Officer

Mr. Bowdring, joined the Company as its Corporate Controller in October 2008. In January 2009, the Company appointed Mr. Bowdring as its Chief Financial Officer (and principal accounting officer), and he served in this capacity until March 2013. When his service as Chief Financial Officer (and principal accounting officer) ended in March 2013, he became a member of the Board of Directors and a consultant. Mr. Bowdring has served, and continues to serve, as a Director of and consultant to INVO Bioscience. Further, on September 20, 2016, he was elected Treasurer and Secretary of INVO Bioscience, and on March 6, 2017 he was elected Acting Chief Financial Officer (and acting principal accounting officer), all positions in which he has continued to serve and currently serves. Currently Mr. Bowdring is the Chief Financial Officer of Dynasil Corporation of America, he joined Dynasil in March 2013. From April 2003 to August 2008, Mr. Bowdring served as CFO & Vice President of Finance and Administration for Cyphermint, Inc., a software development firm. For the fourteen prior years, he was the Controller and Vice President of Lifeline Systems Inc., a public manufacturing and service company (NASDAQ: LIFE) in the personal emergency response market. Mr. Bowdring has a strong history in senior financial management with more than 35 years' experience serving in capacities such as chief financial officer, vice president of finance and controller. Rob has been in both public and private manufacturing and service companies during his career. Mr. Bowdring has a Bachelor's Degree in Accounting from the University of Massachusetts in Amherst.

Michael J. Campbell, Director (Effective October 11, 2017)

Mr. Campbell is the Vice President of IVF Americas Business Unit for Cooper Surgical, Inc. (CSI), a wholly owned subsidiary of The Cooper Companies (NYSE: COO). Mr. Campbell has substantial medical device sales, marketing and business development leadership experience within Global Fortune 500 and Start-up Company environments. During his over 11-year career at Cooper Surgical, Mike has been responsible for IVF product portfolio sales globally including the US, Canada, Latin America, Europe, Middle East, Africa, and Asia Pacific regions. In addition to Mr. Campbell's current position as Vice President of IVF Americas Business Unit, he served in various leadership roles including Vice President of International Business Unit from 2013-2014 and as Vice President of IVF Business Unit from 2006 to 2012. Prior to joining Cooper Surgical, Mike was Vice President of Sales, Marketing and Business Development at Retroactive Bioscience from 1997 to 2006 and Vice President of Sales and Marketing for Gabriel Medical from 1994 to 1997. Mr. Campbell also served in various senior management positions across marketing, sales and product management at Boston Scientific Corporation beginning in 1984 through 1994.

Steven M. Shum, Director (Effective October 11, 2017)

Mr. Shum is Chief Financial Officer of Eastside Distilling (NASDAQ: ESDI) since October 2015. Prior to joining Eastside, Mr. Shum served as an Officer and Director of XZERES Corp, a publicly-traded global renewable energy company, from October 2008 until April 2015 in various officer roles, including Chief Operating Officer from September 2014 until April 2015, Chief Financial Officer, Principal Accounting Officer and Secretary from April 2010 until September 2014 (under former name, Cascade Wind Corp) and Chief Executive Officer and President from October 2008 to August 2010. Mr. Shum also serves as the managing principal of Core Fund Management, LP and the Fund Manager of Core Fund, LP. He was a founder of Revere Data LLC (now part of Factset Research Systems, Inc.) and served as its Executive Vice President for four years, heading up the product development efforts and contributing to operations, business development, and sales. He spent six years as an investment research analyst and portfolio manager of D.N.B. Capital Management, Inc. His previous employers include Red Chip Review and Laughlin Group of Companies. He earned a B.S. in Finance and a B.S. in General Management from Portland State University in 1992.Group of Companies. He earned a B.S. in Finance and a B.S. in General Management from Portland State University in 1992.

Independent Committees, Audit, Compensation and Nominating

The Company currently has not established committees with a majority of independent directors but it intends to do so in the future.

Code of Ethics

We have adopted a Code of Conduct that applies to all employees including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. The text of our Code of Conduct is posted in the "Investor Information—Corporate Governance" section of our website, www.INVOBioscience.com.We intend to disclose on our website any amendments to, or waivers from, our Code of Business Conduct and Ethics that are required to be disclosed pursuant to the disclosure requirements of Item 5.05 of Form 8-K

Cumulative voting is not provided for in our amended and restated articles of incorporation or any amendments thereto. Directors are elected by a majority vote of the directors in office. The common stock is not entitled to preemptive rights and is not subject to conversion or redemption. Upon the occurrence of a liquidation, dissolution or winding-up, the holders of shares of outstanding common stock are entitled to share ratably in all assets remaining after payment of liabilities and satisfaction of preferential rights of any outstanding preferred stock. There are no sinking fund provisions applicable to the common stock.

EXECUTIVE COMPENSATION

Executive Compensation

Summary Compensation Table

The following Summary Compensation Table sets forth, for the years indicated, all cash compensation paid, distributed or accrued for services, including salary and bonus amounts, rendered in all capacities by the Company's "named executive officers" for SEC reporting purposes. Note, none of our officers received cash compensation during fiscal 2007 and the years 2010 through 2017.

SUMMARY COMPENSATION TABLE

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Award ($)	All other Compensation ($)	Total ($)
Kathleen Karloff	2018	$ 120,000	$ 0	$ 23,000	$ 0	$ 143,000
CEO, President	2017	$ 120,000	$ 0	$ 0	0	120,000
Chairperson Director (1 & 3)						
Robert Bowdring	2018	$ 120,000	$ 0	$ 23,000	$ 0	$ 143,000
Director (March 2013 to date & Consultant) (2 & 3)	2017	$ 120,000	$ 0	$ 0	0	120,000

(1) Due to the lack of funding, Ms. Karloff's salary has been accrued and not paid to Ms. Karloff. In 2018, approximately $405,671 of this accrued compensation was converted into 1,040,183 shares of common stock.

(2) Due to the lack of funding, a portion of Mr. Bowdring's salary has been accrued and not paid to Mr. Bowdring. In 2018 and 2017 the amount of salary accrued was $45,000 and $120,000 respectively. In 2018, approximately $396,210 of this accrued compensation was converted into 1,015,924 shares of common stock.

(3) During 2017 and 2018 the named officers did not receive any of their compensation in order to assist the Company's cash flow during this time period, such amounts have been accrued together with compensation from prior years and are reflected as a liability on the balance sheet. For this effort it was decided that the named officers would receive stock grants. The per share price was generally based on the average closing market price over a period of time prior to the date of issue.

Employment Contracts

Executives do not have employment agreements with the Company.

Compensation of Directors

In November 2017, the board expanded to five directors and nominated two independent board of directors to fill the vacancies. We use the definition of "independence" standards as defined in the OTCQB Standards which provides that an "independent director" is a person other than an executive officer or employee of the company or any other individual having a relationship, which, in the opinion of the Company's board of directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. We have determined that Michael Campbell and Steven Shum are independent directors.

Each independent board member received 200,000 shares of restricted INVO Bioscience common stock for their services from November 2017 to October 2018. These shares were issued in January 2018. In October 2018, each independent Director was issued 400,000 shares of restricted common stock, 200,000 shares were for the work provided by the Directors throughout 2018 and 200,000 shares were provided in advance as their 2019 Director's compensation. In addition pursuant to an oral consulting agreement Mr. Bowdring has been accruing compensation for his oversight of the financial and administrative areas of the company at a rate of $10,000 per month as reflected in the table above. Our directors also receive reimbursement of out-of-pocket expenses incurred in attending Board and committee meetings.

In January 2018, each board member received 200,000 shares of restricted INVO Bioscience common stock for their service as a board member for 2018. Ms. Karloff, our Chairperson, President and Chief Executive Officer, does not receive any compensation for her Board service beyond the compensation she receives as an executive officer of the Company:

DIRECTOR COMPENSATION TABLE

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)(2)	Option Awards ($)	Total ($)(1)
Kevin Doody, MD	–	$ 179,000	–	$ 179,000
Michael Campbell	–	$ 179,000	–	$ 179,000
Steven Shum	–	$ 179,000	–	$ 179,000

(1) The amounts shown in this column represent the aggregate grant date fair value of stock awards granted in the year computed in accordance with FASB ASC Topic 718.

(2) For the director compensation year beginning January 2018, the three independent directors. The annual stock grants for the director compensation year beginning January 2018 was made on January 22, 2018, 200,000 shares were issued at the grant date closing market price of $0.115 with a value of $23,000 each, and on October 31, 2018 400,000 shares were issued to Dr. Doody, Mr. Campbell and Mr. Shum at the grant date closing market price of $0.39 per share with a value of $156,000.

Outstanding Equity Awards

The Company has not issued any equity award plans.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

We describe below transactions and series of similar transactions, during the last three fiscal years, to which we were a party, in which:

- The amounts involved exceed or will exceed the lesser of $120,000 or one percent (1%) of our average total assets at year end for the last two completed fiscal years; and
- Any of our directors or executive officers, or any member of the immediate family of any of the foregoing person, who had or will have a direct or indirect material interest.

The Company has entered into several transactions with James Bowdring, the brother of the Company's Director, Treasurer and Secretary Robert Bowdring.

In May 2018, the company issued a series of convertible notes to James Bowdring and family in the aggregate amount of $40,000.The convertible notes bear interest at the rate of 9% per annum. As of June 30, 2019, the outstanding principal balance of the convertible notes is $40,000. See "Note 8 Notes Payable and Other Related Party Transactions."

During the nine months ended September 30, 2018, the Company sold 150,000 shares of common stock at a price of $0.20 per share for proceeds of $30,000 to Charles Mulrey and family, the brother-in-law of Robert J. Bowdring, Director & Acting Chief Financial Officer as part of the recent financing. See "Note 8 Notes Payable and Other Related Party Transactions."

During the second quarter of 2018, INVO Bioscience settled a commitment it had with one of its Directors, Dr. Kevin Doody for the services he and his team performed prior to and following INVOcell's FDA clearance related to clinical guidance and support. The Company issued him 3 million common shares of stock with a fair value of $1,530,000. See "Note 8 Notes Payable and Other Related Party Transactions."

PRINCIPAL STOCKHOLDERS

The following table and notes set forth the beneficial ownership of the common stock of the Company as of April 15, 2019 by (i) each person who was known by the Company to beneficially own more than 5% of the outstanding common stock, (ii) each director and named executive officer, and (iii) all directors and executive officers as a group. Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or dispositive power with respect to the securities. Unless otherwise indicated below, to our knowledge, all persons listed below have sole voting and dispositive power with respect to their shares of our common stock, except to the extent authority is shared by spouses under applicable law. Unless otherwise noted, the address of all of the individuals and entities named below is care of INVO Bioscience, Inc., 407R Mystic Avenue, Suite 34C, Medford, Massachusetts 02155:

Title of Class	Name and Address of Beneficial Owner (1)(2)	Number of Shares	Percentage of Common Stock
Owners of more than 5%:			
Common Stock	Claude Ranoux 88 Chestnut Street Winchester, MA 01889	24,694,000	15.9%
Directors and Executive Officers:			
Common Stock	Kathleen Karloff	14,200,183	9.1%
Common Stock	Robert Bowdring	11,715,942	7.5%
Common Stock	Kevin Doody	5,073,197	3.3%
Common Stock	Michael Campbell	607,800	0.4%
Common Stock	Steven Shum	600,000	0.4%
	All directors and executive officers as a group (5 persons)	**58,891,122**	**36.6%**

(1) Beneficial ownership is determined in accordance with Rule 13d-3(a) of the Securities Exchange Act of 1934 and generally includes voting or investment power with respect to securities. Except as indicated by footnotes and subject to community property laws, where applicable, the person named above has sole voting and investment power with respect to all shares of the Common Stock shown as beneficially owned by him or her. The number of shares outstanding on April 15, 2019 was 154,711,112.

(2) Unless otherwise indicated, the business address of each current director or executive officer is INVO Bioscience, Inc. 407 Rear Mystic Avenue, Suite 34C, Medford, Massachusetts 02155.

Changes in Control

There are no present arrangements, including pledges of the Company's securities, known to the Company, the operation of which may result at a subsequent date in a change in control of the Company.

LEGAL MATTERS

The validity of the issuance of the common stock offered hereby will be passed upon for us by Shulman, Rogers, Gandal, Pordy & Ecker, P.A..

EXPERTS

The financial statements for the two most recent fiscal years ended December 31, 2018 and 2017, have been audited by Liggett & Webb P.A. an independent registered public accounting firm, to the extent and for the periods set forth in their report, which contains an explanatory paragraph regarding our ability to continue as a going concern, appearing elsewhere herein and in the registration statement, and are included in reliance upon such report given upon the authority of said firms as experts in auditing and accounting.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act that registers the shares of our common stock to be sold in this offering. The registration statement, including the attached exhibits and schedules, contains additional relevant information about the Company and our capital stock. The rules and regulations of the SEC allow us to omit from this prospectus certain information included in the registration statement. For further information about the Company and our common stock, you should refer to the registration statement and the exhibits and schedules filed with the registration statement. With respect to the statements contained in this prospectus regarding the contents of any agreement or any other document, in each instance, the statement is qualified in all respects by the complete text of the agreement or document, a copy of which has been filed as an exhibit to the registration statement.

We file reports, proxy statements and other information with the SEC under the Exchange Act. You may read and copy this information from the Public Reference Room of the SEC, 100 F Street, N.E., Room 1580, Washington, D.C. 20549, at prescribed rates. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet website that contains reports, proxy statements and other information about issuers, like us, that file electronically with the SEC. The address of that website is www.sec.gov.

You should rely only on the information provided in this prospectus or any prospectus supplement. We have not authorized anyone else to provide you with different information. We are not making an offer to sell, nor soliciting an offer to buy, these securities in any jurisdiction where that would not be permitted or legal. Neither the delivery of this prospectus nor any sales made hereunder after the date of this prospectus shall create an implication that the information contained herein or our affairs have not changed since the date hereof.

INVO BIOSCIENCE, INC.
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INVO BIOSCIENCE, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2019	December 31, 2018
ASSETS	(unaudited)	
Current assets		
Cash	$ 3,057,466	$ 212,243
Accounts receivable net	74,717	225,899
Inventory, net	51,685	43,513
Prepaid expense and other current assets	226,696	249,454
Total current assets	3,410,564	731,109
Property and equipment, net	81,709	34,446
Other Assets:		
Capitalized patents, net	10,958	11,792
Total other assets	10,958	11,792
Total assets	$ 3,503,231	$ 777,347
LIABILITIES AND STOCKHOLDERS' DEFICIENCY		
Current liabilities		
Accounts payable and accrued liabilities, including related parties	$ 588,354	$ 571,828
Accrued compensation	932,661	2,515,256
Deferred revenue	4,840,323	18,895
Note payable	-	131,722
Note payable - related party	35,000	97,743
Convertible notes, net of discount	196,883	157,039
Convertible notes, related party - net of discount	12,480	9,087
Total current liabilities	6,605,701	3,501,570
Commitments and contingencies	-	-
Stockholder's deficiency		
Preferred Stock, $.0001 par value; 100,000,000 shares authorized; No shares issued and outstanding as of March 31, 2019 and December 31 2018, respectively	-	-
Common Stock, $.0001 par value; 200,000,000 shares authorized; 154,621,112 and 154,292,497 issued and outstanding as of March 31, 2019 and December 31, 2018, respectively	15,461	15,429
Additional paid-in capital	19,061,861	18,981,570
Accumulated deficit	(22,179,792)	(21,721,222)
Total stockholder's deficiency	(3,102,470)	(2,724,223)
Total liabilities and stockholders' deficiency	$ 3,503,231	$ 777,347

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

INVO BIOSCIENCE, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)

	For the Three Months Ended March 31, 2019	For the Three Months Ended March 31, 2018
Revenue	$ 189,432	$ 104,140
Cost of Goods Sold:	10,978	14,424
Gross Margin	178,454	89,716
Selling, general and administrative expenses	527,565	229,999
Total operating expenses	527,565	229,999
Loss from operations	(349,111)	(140,283)
Other (income) expense:		
Interest expense	109,459	4,440
Total other (income) expenses	109,459	4,440
Loss before income taxes	(458,570)	(144,723)
Provisions for income taxes	-	-
Net Loss	$ (458,570)	$ (144,723)
Basic net loss per weighted average shares of common stock	$ (0.00)	$ (0.00)
Diluted net loss per weighted average shares of common stock	$ (0.00)	$ (0.00)
Basic weighted average number of shares of common stock	154,102,856	143,340,969
Diluted weighted average number of shares of common stock	154,102,856	143,340,969

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

INVO BIOSCIENCE, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIENCY
(unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Amount			
Balance, December 31, 2017	**142,132,374**	**$ 14,213**	**$ 13,638,806**	**$ (18,645,131)**	**$ (4,992,112)**
Common stock issued for cash	260,000	26	46,974	-	47,000
Common stock issued to employees	1,200,000	120	137,880	-	138,000
Common stock issued for services	352,326	35	43,629	-	43,664
Net loss for the three months ended March 31, 2018	-	-	-	(144,723)	(144,723)
Balance, March 31, 2018 (unaudited)	**143,944,700**	**$ 14,394**	**$ 13,867,289**	**$ (18,789,854)**	**$ (4,908,171)**
Balance, December 31, 2018	**154,292,497**	**$ 15,429**	**$ 18,981,570**	**$ (21,721,222)**	**$ (2,724,223)**
Common stock issued for services	60,000	6	26,594	-	26,600
Conversion of notes payable and accrued interest	268,615	26	53,697	-	53,723
Net loss for the three months ended March 31, 2019	-	-	-	(458,570)	(458,570)
Balance, March 31, 2019 (unaudited)	**154,621,112**	**$ 15,461**	**$ 19,061,861**	**$ (22,179,792)**	**$ (3,102,470)**

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

INVO BIOSCIENCE, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)

	For the Three Months Ended March 31, 2019	For the Three Months Ended March 31, 2018
Cash flows from operating activities:		
Net loss	$ (458,570)	$ (144,723)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Non-cash stock compensation issued for services	26,600	181,664
Depreciation and amortization	1,971	1,134
Amortization of discount on notes payable	93,237	-
Changes in assets and liabilities:		
Accounts receivable	151,182	(24,160)
Inventories	(8,172)	3,939
Prepaid expenses and other current assets	22,758	(12,523)
Deferred revenue	4,821,428	-
Accounts payable and accrued expenses	20,249	(124,884)
Accrued compensation	(1,582,595)	82,200
Net cash provided by (used in) operating activities	3,088,088	(37,353)
Cash from investing activities:		
Payments to acquire property, plant and equipment	(48,400)	-
Net cash used in investing activities	(48,400)	-
Cash from financing activities:		
Cash paid for related party notes payable	(62,743)	-
Cash paid for notes payable	(131,722)	-
Proceeds from the sale of common stock	-	47,000
Net cash (used in) provided by financing activities	(194,465)	47,000
Increase in cash and cash equivalents	2,845,223	9,647
Cash and cash equivalents at beginning of period	212,243	25,759
Cash and cash equivalents at end of period	$ 3,057,466	$ 35,406
Supplemental disclosure of cash flow information:		
Cash paid during the period for:		
Interest	$ 9,879	$ -
Taxes	$ 912	$ 912
Common stock issued for conversion of notes payable and accrued interest	$ 53,723	$ -

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

INVO BIOSCIENCE, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2019
(unaudited)

Note 1 – Basis of Presentation

The accompanying unaudited condensed consolidated balance sheets as of March 31, 2019 and December 31, 2018, the condensed consolidated statements of operations, stockholders' deficiency and cash flows for the three months ended March 31, 2019 and 2018 of INVO Bioscience, Inc. (the "Company"), and the related information contained in these notes have been prepared by management and are unaudited. In the opinion of management, all adjustments (which include normal recurring and nonrecurring items) necessary to present fairly the Company's financial position, results of operations and cash flows in conformity with generally accepted accounting principles for the periods presented have been made. Interim operating results are not necessarily indicative of operating results for a full year.

The preparation of our unaudited condensed consolidated financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the unaudited condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting periods. Certain information and note disclosures normally included in the Company's annual financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted. These unaudited condensed consolidated financial statements should be read in conjunction with the financial statements and notes thereto included in the Company's December 31, 2018 Annual Report on Form 10-K previously filed by the Company with the Securities and Exchange Commission (SEC).

The Company considers events or transactions that have occurred after the unaudited condensed consolidated balance sheet date of March 31, 2019, but prior to the filing of the unaudited condensed consolidated financial statements with the SEC on this Quarterly Report on Form 10-Q, to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure, as applicable. Subsequent events have been evaluated through the date of the filing of this Quarterly Report on Form 10-Q with the SEC.

Note 2 – Recent Accounting Pronouncements

Changes to GAAP are established by the Financial Accounting Standards Board ("FASB") in the form of accounting standards updates ("ASUs") to the FASB's Accounting Standards Codification.

The Company considers the applicability and impact of all ASUs. ASUs not listed below were assessed and determined not to be applicable or are expected to have minimal impact on the Company's consolidated financial position and results of operations.

Recently Adopted Accounting Pronouncements

In February 2016, FASB issued ASU 2016-02, Leases ("ASU 2016-02"). The new standard establishes a right-of-use ("ROU") model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The adoption of the new standard did not have an impact on the Company's consolidated financial statements.

Note 3 – Going Concern

On January 14, 2019, INVO Bioscience entered into a distribution agreement (the "Distribution Agreement") with Ferring International Center S.A. ("Ferring") granted to Ferring exclusive licensing rights to sublicense the Company's INVOcell together with the retention device. Under the terms of the Distribution Agreement, Ferring was obligated to make an initial payment to the Company of $5,000,000 upon satisfaction of certain closing conditions. The Company received the initial $5 million cash payment received upon the execution of the Ferring distribution agreement in January 2019 and as a result believes its cash on hand will be sufficient to fund its current debt obligations, estimated capital expenditures and working capital needs for the next twelve to eighteen months.

INVO BIOSCIENCE, INC.
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Note 4 – Inventory

As of March 31, 2019 and December 31, 2018, the Company recorded the following inventory balances:

	March 31, 2019	December 31, 2018
Work in Process	$ 42,428	$ 30,689
Finished Goods	9,257	12,824
Total Inventory, net	$ 51,685	$ 43,513

Note 5 – Property and Equipment

The estimated useful lives and accumulated depreciation for furniture, equipment and software are as follows as of March 31, 2019 and December 31, 2018:

	Estimated Useful Life
Molds	3 to 7 years

	March 31, 2019	December 31, 2018
Manufacturing Equipment- Molds	$ 118,763	$ 70,363
Accumulated Depreciation	(37,054)	(35,917)
Total	**$ 81,709**	**$ 34,446**

During the three months ended March 31, 2018 and 2017 the Company recorded depreciation expense of $1,137 and $0, respectively. The Company began shipping its new retention device in August 2018 which triggered the start of depreciating our retention device mold during the current quarter.

Note 6 – Patents

As of March 31, 2019 and December 31, 2018, the Company recorded the following patent balances:

	March 31, 2019	December 31, 2018
Total Patents	$ 77,743	$ 77,743
Accumulated Amortization	(66,785)	(65,951)
Patent costs, net	**$ 10,958**	**$ 11,792**

During the three ended March 31, 2019 and 2018, the Company recorded $834 and $1,134 in amortization expenses respectively.

Estimated amortization expense as of March 31, 2019 is as follows:

Years ended December 31,	
2019	$ 4,536
2020	1,809
2021	1,809
2022 and thereafter	2,804
Total	$ 10,958

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Note 7 – Notes Payable

Notes Payable

In August 2016, INVO Bioscience converted a long time vendor's outstanding accounts payable balance of $131,722 into a Promissory Note with a three year term that accrues interest at 5% per annum. The note provides for interest only payments on the first and second anniversaries of the note. The note is payable in full along with any outstanding accrued interest on August 9, 2019. The Company has the right to prepay the note at any time without a premium or penalty which it did in January 2019. The interest on this note for the three months ended March 31, 2019 and 2018 were $489 and $1,647, respectively. The Note and all accrued interest was paid in full and as of March 31, 2019, the balance is $0.

2018 Convertible Notes Payable

In April and May 2018, the Company issued convertible notes (the "2018 Convertible Notes") payable to investors' in the aggregate principal amount of $895,000. The 2018 Convertible Notes accrue interest at the rate of 9% per annum which is paid in stock. 2018 Convertible Notes with an aggregate principal amount of $550,000 are due on January 30, 2021, and 2018 Convertible Notes with an aggregate principal amount of $345,000 are due on March 31, 2021. The notes are convertible into shares of common stock at a price of $0.20 per share, provided, that if the Company completes a subsequent equity financing, the holders of the 2018 Convertible Notes can elect to convert the notes in shares of our common stock at a price equal to 75% of the price paid per share in such subsequent equity financing. During the fourth quarter of 2018, three note holders converted their notes with a value of $200,000 into 1,055,415 shares of common stock. During the three months ended March 31, 2019, a note holder converted principal and accrued interest of $50,000 and $3,723, respectively, into 268,615 shares of common stock.

The Company calculated a beneficial conversion feature of the 2018 Convertible Notes based on ASU 17-11 in the form of a discount of $895,000; $93,237 and $0 of this amount was amortized to interest expense during the three months ended March 31, 2019 and 2018, respectively, based on the three year term of the notes. $37,377 was also amortized for a note that was converted during the first quarter of 2019. In addition $14,870 and $0 of interest was expensed in the three months ended March 31, 2019 and 2018, respectively.

Note 8 – Notes Payable and Other Related Party Transactions

On September 18, 2008, the Company entered into a related party transaction with Dr. Claude Ranoux. Dr. Ranoux was then the President, Director and Chief Scientific Officer of the Company; as of the date of this filing he is a Director. Dr. Ranoux had loaned funds to the Company to sustain its operations since January 5, 2007 (inception). Dr. Ranoux's total original cumulative investment as of December 31, 2008 was $96,462, as of December 31, 2017 and 2016 it is $21,888 ("the Principal Amount") in INVO Bioscience. On March 26, 2009, the Company and Dr. Ranoux agreed to re-write the agreement to a non-convertible note payable bearing interest at 5% per annum, the term of the note had been extended, and has been extended a couple of additional times, the current repayment date is October 31, 2018. The Company and Dr. Ranoux can jointly decide to repay the loan earlier without prepayment penalties. During the twelve months ended December 31, 2018 the outstanding balance of $21,888 was paid in full including all interest due, in 2017, $0 was repaid on the principal of the loan.

On March 5, 2009, the Company entered into a related party transaction with Kathleen Karloff, the Chief Executive Officer and a Director of the Company. Ms. Karloff provided a short-term loan in the amount of $75,000 bearing interest at 5% per annum to the Company to fund operations. In May 2009, Ms. Karloff loaned to the Company an additional $13,000, making her total cumulative loan $88,000 as of December 31, 2011. This note was due on September 15, 2009, which has since been extended a few times to its current date of October 31, 2018. During the twelve months ended December 31, 2014, Ms. Karloff loaned the Company an additional $66,000 at an interest rate of 0% by entering into a note payable agreement in satisfaction of expenses incurred by her for amounts previously advanced to the Company. This note currently has the same expiration date as the others which is October 31, 2018. During the twelve months ended December 31, 2018 $91,257 was paid against the principal of the loan, in 2017, $0 was repaid on the principal of the loan. The principal balances of the loan was $62,743 and $154,000 as of December 31 2018 and 2017 respectively. The related interest for the twelve months ended December 31, 2018 and 2017 was $15,278 and $4,400 respectively. During the three months ended March 31, 2019, the Company paid the remaining balance due Ms. Karloff in the amount of $62,743.

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In December 2009, James Bowdring, the brother of Director Robert Bowdring invested $100,000 acquiring 666,667 shares of restricted common stock. In April 2011, the Company issued a new short term convertible note ("Q211 Note") payable to James Bowdring in the amount of $50,000. The Note carries a 10% interest rate. The note has a current balance of $25,000. The Q211 Note is convertible into Common Stock of the Company at a conversion price of $0.03 per share, subject to adjustments. During the three months ended March 31, 2019, the Company accrued interest in the amount of $616 on the Q211 Note.

In November 2011, the Company issued a new convertible note ("Q411 Note") payable to James Bowdring in the amount of $10,000. The Q411 Note carries a 10% interest rate. The Q411 Note is convertible into Common Stock of the Company at a conversion price of $0.01 per share, subject to adjustments. During the three months ended March 31, 2019, the Company accrued interest in the amount of $247 on the Q411 Note.

In May 2018, James Bowdring and his children participated in the "2018 Convertible Notes" offerings in the aggregate principal amount of $40,000. The 2018 Convertible Notes accrue interest at the rate of 9% per annum which is paid in stock. These Notes are due on March 31, 2021. The notes are convertible into shares of common stock at a price of $0.20 per share, provided, that if the Company completes a subsequent equity financing, the holders of the 2018 Convertible Notes can elect to convert the notes in shares of our common stock at a price equal to 75% of the price paid per share in such subsequent equity financing.

The Company has been renting our corporate office from Forty Four Realty Trust which is owned by James Bowdring, the brother of Director & Acting Chief Financial Officer, Robert Bowdring since November 2012. It is a month to month rental arrangement for what the Company believes is less than the fair market real estate rental rate for comparable leases. The current rent is $600 per month, or $7,200 annually. In addition the Company purchases stationary supplies and marketing items at discounted rates from Superior Printing & Promotions which is also owned by James Bowdring and is in the same building as our corporate office. INVO Bioscience spent $778 and $234 with Superior during the first three months of 2019 and 2018, respectively.

Principal balances of the Related Party loans were as follows:

	March 31, 2019	December 31, 2018
James Bowdring Family - 2011 Notes	35,000	35,000
James Bowdring Family – 2018 Convertible Notes	40,000	40,000
Kathleen Karloff Note	-	62,743
Less discount	(27,520)	(30,913)
Total, net of discount	$ 47,480	$ 106,830

Interest expense on the Related Party loans was $1,751 and $2,792 for the three months ended March 31, 2019 and 2018, respectively.

Accounts payable and accrued liabilities balances include expenses reports for Ms. Karloff and Mr. Bowdring for expenses they paid for personally related to travel or normal business expenses. As of March 31, 2019 they were $1,762 and as of December 31, 2018, they were $1,676.

Note 9 – Stockholders' Equity

Three Months Ended March 31, 2019

In January 2019, pursuant to Section 4(a)(2) of the Securities Act, the Company issued 60,000 shares of common stock with a fair value of $26,600 to service providers.

In February 2019, pursuant to Section 4(a)(2) of the Securities Act, the Company issued 268,615 shares of common stock for conversion of notes payable and accrued interest in the amount of $53,723.

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Three Months Ended March 31, 2018

In January and March 2018, pursuant to Section 4(a)(2) of the Securities Act, the Company sold 260,000 shares of common stock to accredited investors in a private placement for cash of $47,000.

In January 2018, pursuant to Section 4(a)(2) of the Securities Act, the Company issued 1,200,000 shares of common stock with a fair value of $138,000 to management and board members.

In January and March 2018, pursuant to Section 4(a)(2) of the Securities Act, the Company issued 352,326 shares of common stock with a fair value of $43,664 to service providers.

Note 10 – Stock Options and Warrants

As of March 31, 2019 and December 31, 2018, the Company does not have any outstanding or committed and unissued stock options or warrants.

Note 11 – Income Taxes

The Company has adopted ASC 740-10, which requires the recognition of deferred tax liabilities and assets for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax liabilities and assets are determined based on the difference between financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse.

The Company's total deferred tax liabilities, deferred tax assets and deferred tax asset valuation allowances at March 31, 2019 and December 31, 2018 are as follows:

	March 31, 2019	December 31, 2018
Total deferred tax assets	$ 4,240,000	$ 4,124,000
Less valuation allowance	(4,240,000)	(4,124,000)
Total deferred tax liabilities	-	-
Net deferred tax asset (liability)	$ -	$ -

Realization of deferred tax assets is dependent on future earnings, if any, the timing and amount of which is uncertain. Those amounts are therefore presented on the Company's balance sheets as a non-current asset. Utilization of the net operating loss carry forwards may be subject to substantial annual limitations, which may result in the expiration of net operating loss carry forwards before utilization.

Note 12 – Commitments and Contingencies

A) Operating Leases

In November 2012, INVO Bioscience entered into a month-to-month rental agreement with Four Forty Realty Trust with for the space it requires. Four Forty Realty Trust is owned by investor James Bowdring, the brother of Director & Acting Chief Financial Officer Robert Bowdring. The annual rent under the agreement is $7,200 annually.

B) Litigation

INVO BIOSCIENCE, INC.
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There has been no change in the status of the litigation INVO Bioscience, Inc., and two of its directors have been involved in since 2010, defending litigation brought by investors in an alleged predecessor of INVO Bioscience. On March 24, 2010, INVO Bioscience, Inc. and its corporate affiliate, Bio X Cell, Inc., Claude Ranoux, and Kathleen Karloff were served an Amended Complaint, the original of which was filed on December 31, 2009 at the Suffolk Superior Court Business Litigation Session by two terminated employees of Medelle Corporation (also named as a co-defendant but no longer active), who are also attorneys, and a former investor in and creditor of Medelle. These plaintiffs allege various claims of wrongdoing relating to the sale of assets of Medelle to Dr. Ranoux. Plaintiffs claim that Dr. Ranoux, Ms. Karloff, and Medelle (and therefore INVO Bioscience as an alleged successor corporation) violated alleged duties owed to plaintiffs in connection with the sale. Separate claims were also alleged against INVO Bioscience.

Dr. Ranoux, Ms. Karloff, and INVO Bioscience have challenged these allegations, which they believe are baseless. The transfer of the assets of Medelle was professionally handled by an independent third party, after approval by the Medelle Board of Directors, representing a majority of its shareholders. Medelle's Board voted to proceed with an assignment for the benefit of creditors (AFBC) and gave complete authority to the President & CEO at that time (neither Dr. Ranoux nor Ms. Karloff) to work with the third-party assignee and to get the best possible price for those assets. The third party was responsible for notifying all the appropriate parties and for filing notices in various professional publications and newspapers of Medelle's intention to sell its assets. The third party also contacted numerous large medical device and bio-pharma companies to learn if they would be interested in acquiring the assets. After a private sale was deemed unlikely, the assignee of the assets elected to proceed with a sealed-bid auction of the assets. On the day of the auction, Dr. Ranoux submitted the only bid and was awarded the assets, upon full payment.

During 2010, Dr. Ranoux, Ms. Karloff, and INVO Bioscience filed Motions to Dismiss as to all claims, pursuant to M.R.Civ. P. 12(b)(6). In a written Decision rendered on November 12, 2010, the judge dismissed all claims against INVO, Bio X Cell, and Ms. Karloff, and also dismissed the claims against Dr. Ranoux alleging civil conspiracy and breach of M.G.L. c. 93A. The judge denied Dr. Ranoux's motion to dismiss the remaining breach of fiduciary duty and fraud claims. The plaintiffs allege in their Amended Complaint that Dr. Ranoux committed fraud by failing to inform them of the details of the Medelle auction.

The claims against Dr. Ranoux that survived the November 2010 dismissal order were submitted to binding arbitration. On February 15, 2013, the mutually-agreed arbitrator ruled in favor of Dr. Ranoux. The award held that Dr. Ranoux did not withhold information about the auction of Medelle's assets and expressed doubt that the plaintiffs would have invested the resources necessary to make a beneficial use of the assets. The arbitrator's award then was confirmed by the Superior Court on August 21, 2013. The Superior Court's confirmation of the award was affirmed on appeal on October 20, 2013 by the Massachusetts Appeals Court. The Massachusetts Supreme Judicial Court then denied further appellate review.

On October 18, 2016, following motions and argument, the Superior Court issued a memorandum of decision and order denying plaintiffs' motion for entry of default judgment and assessment of damages against Medelle and allowed the motion of INVO Bioscience, Bio X Cell, and Ms. Karloff for entry of final judgment of dismissal. The foregoing order was converted to a final judgment dismissing all claims against all defendants and entered on the docket on October 27, 2016.

On November 28, 2016, plaintiffs filed an amended notice of appeal from the Superior Court's decision of October 17, 2016 and the subsequent judgment entered on October 27, 2016. The appeal further challenges the order of dismissal from November, 2010. Plaintiffs did not appeal from the dismissal of the claims against Ms. Karloff, so the judgment in her favor is now final, leaving claims against INVO Bioscience, Bio X Cell, Medelle, and Dr. Ranoux.

INVO Bioscience and Bio X Cell intend a vigorous opposition to the current appeal, consistent with their previous positions that no breach of duty occurred in the sale of Medelle's assets. It is assumed that Dr. Ranoux will oppose the appeal as well.

Outside of the above-mentioned litigation, neither INVO Bioscience nor Bio X Cell, our wholly-owned subsidiary, either directly or indirectly, are involved in any lawsuit outside the ordinary course of business, the disposition of which would have a material effect upon either our results of operation, financial position, or cash flows.

C) Employee Agreements

The Company is in the process of writing employment agreements for its current officers, executives and employees of the Company.

D) Consulting Agreements

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The Company has a verbal agreement beginning in March, 2013 with its former CFO, Robert Bowdring, who is currently a Director & Acting Chief Financial Officer, to assist where necessary in the financial and administrative areas of the Company for compensation to be equivalent to the others working in the organization.

Note 13 – Contracts with Customers

We have adopted ASC 606, *Revenue from Contracts with Customers* effective January 1, 2018 using the modified retrospective method applied to those contracts which were not substantially completed as of January 1, 2018. These standards provide guidance on recognizing revenue, including a five-step model to determine when revenue recognition is appropriate. The standard requires that an entity recognize revenue to depict the transfer of control of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. Revenues for 2018 are reported under ASC 606, while prior period amounts are not adjusted and continue to be reported under ASC 605, *Revenue Recognition*.

Revenues for products, including: INVOcell®, INVO ™ Retention System, and INVO Microscope Holding Block are typically recognized at the time the product is shipped, at which time the title passes to the customer, and there are no further performance obligations. Revenues from consignment are recognized when the medical device is shipped from the Consignor to the customer.

In January, 2019 we announced a U.S. license and distribution agreement with Ferring International Center S.A. ("Ferring") and as a result took a significant step to strengthen the Company that we believe will allow us to implement our overall business plan. We believe that this strategic partnership with a strong reproductive organization such as Ferring Pharmaceuticals will provide us with the necessary sales and marketing resources within the United States to expand the market and help reach all of those couples not receiving reproductive treatments today. The agreement calls for the issuance of an initial upfront payment of $5 million which we received upon the signing of the agreement and then subsequent licensing fee payment of $3,000,000 that will provide us with a source of non-dilutive financing to execute our plan. Under the terms of the agreement we can pursue developing international markets and as well as partnering and opening INVO-only reproductive centers within the U.S. market. We believe this major milestone and agreement is a critical step that allows the Company to implement its mission of expanding access to care in the fertility marketplace.

Under the terms of the Distribution Agreement, Ferring completed its obligation to make an initial payment to the Company of $5,000,000 upon completion of the required closing conditions, including executed agreements from all current manufacturers of the Licensed Product that upon a material supply default by the Company, Ferring can assume a direct purchase relationship with such manufacturers. Ferring is obligated to make a second payment to the Company of $3,000,000 provided that the Company is successful in obtaining a five (5) day label enhancement from the FDA for the current incubation period for the Licensed Product at least three (3) years prior to the expiration of the term of the license for the Licensed Product and provided further that Ferring has not previously exercised its right to terminate the Distribution Agreement for convenience. In addition, the Company entered into a separate Distribution Agreement. The Distribution Agreement has an initial term expiring on December 31, 2025 and at the end of the initial term it may be terminated by the Company if Ferring fails to generate specified minimum revenues to the Company from the sale of the Licensed Product during the final two years of the initial term.

The Ferring license was deemed to be a functional licenses that provide customers with a "right to access" to our intellectual property during the subscription period and, accordingly, revenue is recognized over a period of time, which is generally the subscription period. During the quarter ended March 31, 2019, the Company recognized $178,572 related to the Ferring license agreement.

As of March 31, 2019 and December 31, 2018, the Company had deferred revenues of $4,840,323 and $18,895, respectfully.

INVO BIOSCIENCE, INC.
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Sources of Revenue

We have identified the following revenues disaggregated by revenue source:

Domestic Physicians – direct sales of products concluded in January 2019

Domestic Distributor - sales to Ferring who then sells to physicians

Domestic Licensing fee

International Distributors – direct sales of products.

For the three months ended March 31, 2019 and 2018 the source of revenue was derived from:

	March 31, 2019	March 31, 2018
Domestic Physicians	$ 10,860	$ 104,140
Domestic Licensing & Distribution Fee	178,572	-
Total revenue	$ 189,432	$ 104,140

Contract Balances

We incur agreement obligations on general customer purchase orders and e-mails that have been accepted but unfulfilled. Due to the short duration of time between order acceptance and delivery of the related product, we have determined that the balance related to these obligations is generally immaterial at any point in time. We monitor the value of orders accepted but unfulfilled at the close of each reporting period to determine if disclosure is appropriate.

Warranty

Our general product warranties do not extend beyond an assurance that the product delivered will be consistent with stated specifications and do not include separate performance obligations.

Commissions and Contract Costs

We do not use or offer sales commissions of any type at this time. We generally do not incur incremental charges associated with securing agreements with customers which would require capitalization and recovery over the life of the agreement.

Practical Expedients

Our payment terms for sales direct to customers and distributors are substantially less than the one year collection period that falls within the practical expedient in determination of whether a significant financing component exists.

INVO BIOSCIENCE, INC.
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(unaudited)

Shipping and Handling Charges

Fees charged to customers for shipping and handling of products are included as an offset to the costs for shipping and handling of products included as a component of cost of products.

Taxes Collected from Customers

As our products are used in another service and are exempt, to this point we have not collected taxes. If we were to collect taxes they would be on the value of transaction revenue and would be excluded from product revenues and cost of sales and would be accrued in current liabilities until remitted to governmental authorities.

Effective Date and Transition Disclosures

Adoption of the new standards related to revenue recognition did not have a material impact on our consolidated financial statements, and is not expected to have a material impact in future periods.

Note 14 – Subsequent Events

On April 24, 2019, the Company issued 800,000 shares of common stock in connection with the conversion of a note payable in the principal amount of $160,000.

The Company has evaluated subsequent events through the date the financial statements were released and there were no others.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Invo Bioscience, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Invo Bioscience, Inc. ("Company") as of December 31, 2018 and 2017, and the related consolidated statements of operations, stockholders' deficit, and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has incurred losses from operations since inception and has a net stockholders' deficiency. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are described in Note 2 to the consolidated financial statements. The consolidated financial statements do not include any adjustments that may result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Liggett & Webb, P.A.

We have served as the Company's auditor since 2011.

New York, New York

April 16, 2019

INVO Bioscience, Inc.
CONSOLIDATED BALANCE SHEETS

	December 31, 2018	December 31, 2017
ASSETS		
Current assets		
Cash	$ 212,243	$ 25,759
Accounts receivable net	225,899	86,697
Inventory, net	43,513	58,879
Prepaid expense	249,454	63,050
Total current assets	731,109	234,385
Property and equipment, net	34,446	15,700
Other Assets		
Capitalized patents, net	11,792	16,328
Total other assets	11,792	16,328
Total assets	$ 777,347	$ 266,413
LIABILITIES AND STOCKHOLDERS' DEFICIENCY		
Current liabilities		
Accounts payable and accrued liabilities, including related parties	$ 571,828	$ 960,725
Accrued compensation	2,515,256	3,955,190
Deferred revenue	18,895	-
Note payable - related party	97,743	210,888
Note payable	131,722	-
Convertible notes, net of discount of $497,961	157,039	-
Convertible notes, related party - net of discount of $30,913	9,087	-
Total current liabilities	3,501,570	5,126,803
Note payable - long term	-	131,722
Total liabilities	3,501,570	5,258,525
Commitments and contingencies (Note 12)	-	-
Stockholder's deficiency		
Preferred Stock, $.0001 par value; 100,000,000 shares authorized; No shares issued and outstanding as of December 31, 2018 and 2017, respectively	-	-
Common Stock, $.0001 par value; 200,000,000 shares authorized; 154,292,497 and 142,132,374 issued and outstanding as of December 31, 2018 and 2017, respectively	15,429	14,213
Additional paid-in capital	18,981,570	13,638,806
Accumulated deficit	(21,721,222)	(18,645,131)
Total stockholder's deficiency	(2,724,223)	(4,992,112)
Total liabilities and stockholders' deficiency	$ 777,347	$ 266,413

The accompanying notes are an integral part of these consolidated financial statements.

INVO Bioscience, Inc.

CONSOLIDATED STATEMENTS OF LOSSES

	For the Year Ended December 31, 2018	For the Year Ended December 31, 2017
Revenue	$ 494,375	$ 282,145
Cost of Goods Sold	90,367	51,954
Gross Margin	404,008	230,191
Selling, general and administrative expenses	3,038,068	870,612
Total operating expenses	3,038,068	870,612
Loss from operations	(2,634,060)	(640,421)
Loss on settlement of debt	-	40,869
Interest expense	442,031	20,873
Total other expenses	442,031	61,742
Loss before income taxes	(3,076,091)	(702,163)
Provision for income taxes	-	-
Net Loss	$ (3,076,091)	$ (702,163)
Basic net loss per weighted average shares of common stock	$ (0.02)	$ (0.00)
Diluted net loss per weighted average shares of common stock	$ (0.02)	$ (0.00)
Basic weighted average number of shares of common stock	147,333,051	141,305,050
Diluted weighted average number of shares of common stock	147,333,051	141,305,050

The accompanying notes are an integral part of these consolidated financial statements.

INVO Bioscience, Inc.

CONSOLIDATED STATEMENT OF STOCKHOLDERS' DEFICIENCY

For the Period January 1, 2017 to December 31, 2018

	Common Stock		Additional	Accumulated	
	Shares	Amount	Paid-in Capital	Deficit	Total
Balance, December 31, 2016	**140,596,646**	**$ 14,059**	**$ 13,311,263**	**$ (17,942,968)**	**$ (4,617,646)**
Common stock issued for services	876,672	88	215,044	-	215,132
Common stock issued for cash	318,056	32	54,593	-	54,625
Common stock issued for convertible notes & interest	341,000	34	57,906	-	57,940
Net loss for the twelve months ended December 31, 2017				(702,163)	(702,163)
Balance, December 31, 2017	**142,132,374**	**$ 14,213**	**$ 13,638,806**	**$ (18,645,131)**	**$ (4,992,112)**
Common stock issued for cash	410,000	41	76,959	-	77,000
Common stock issued to directors and employees	6,782,382	678	2,316,555	-	2,317,233
Common stock issued to service providers	3,912,326	391	1,843,273	-	1,843,664
Conversion of notes payable and accrued interest	1,055,415	106	210,977	-	211,083
Discount on convertible notes payable	-	-	895,000	-	895,000
Net loss for the twelve months ended December 31, 2018	-	-	-	(3,076,091)	(3,076,091)
Balance, December 31, 2018	**154,292,497**	**$ 15,429**	**$ 18,981,570**	**$ (21,721,222)**	**$ (2,724,223)**

The accompanying notes are an integral part of these consolidated financial statements.

INVO Bioscience, Inc.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Year Ended December 31, 2018	For the Year Ended December 31, 2017
Cash flows from operating activities:		
Net loss	$ (3,076,091)	$ (702,163)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash stock compensation issued for services	2,092,664	215,132
Loss on settlement of debt	-	40,869
Amortization of discount on notes payable	366,126	-
Depreciation and amortization	5,190	2,810
Changes in assets and liabilities:		
Accounts receivable	(139,202)	(83,903)
Inventories	15,366	26,331
Prepaid expenses and other current assets	200,596	(52,070)
Deferred revenue	18,895	-
Accounts payable and accrued expenses	(377,814)	(5,346)
Accrued interest - related party	-	(1,730)
Accrued compensation	241,299	378,800
Net cash (used) in operating activities	(652,971)	(181,270)
Cash flows from investing activities:		
Payments to acquire property, plant and equipment	(19,400)	-
Net cash (used) in investing activities	(19,400)	-
Cash flows from financing activities:		
Proceeds from the sale of common stock	47,000	54,625
Proceeds from the sale of common stock - related parties	30,000	-
Proceeds from convertible notes payable	855,000	-
Proceeds from convertible notes payable - related parties	40,000	-
Principal payments on note payable - related parties	(113,145)	-
Net cash provided by financing activities	858,855	54,625
Increase (decrease) in cash and cash equivalents	186,484	(126,645)
Cash and cash equivalents at beginning of period	25,759	152,404
Cash and cash equivalents at end of period	$ 212,243	$ 25,759
Supplemental disclosure of cash flow information:		
Cash paid during the period for:		
Interest	$ 6,071	$ -
Taxes	$ 912	$ 912
Common stock issued upon note payable and accrued interest conversion	$ 211,083	$ 57,940
Common stock issued for prepaid services	$ 387,000	$ -
Beneficial conversion feature on convertible notes	$ 895,000	$ -
Common stock issued for accrued compensation	$ 1,681,233	$ -

The accompanying notes are an integral part of these consolidated financial statements.

INVO BIOSCIENCE, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2018 and 2017

NOTE 1 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND ORGANIZATION

(A) General

INVO Bioscience, Inc. ("the Company") offers novel solutions in assisted reproductive technologies while expanding geographic and affordable access to the global reproductive health care community. Our primary focus is the manufacture and sale of the INVOcell device and the INVO technology to assist infertile couples in having a baby. We designed our INVOcell device and our INVO procedure to provide an alternative infertility treatment for the patient and the clinician. The INVO procedure is less expensive and simpler to perform than other comparable infertility treatments. The simplicity of the INVO procedure relates to the ability to potentially perform the INVO procedure in a physician's practice rather than in a specialized facility at a much lower cost overall than current infertility treatments.

We believe that the INVO procedure will make infertility treatment more readily available throughout the world. The INVO procedure is less costly than conventional IVF. The INVOcell device and INVO procedure facilitates conception and embryo development inside the woman's body, rather than in a dish in a laboratory, which is an attractive feature for many couples.

Through December 31, 2018, we have generated minimal revenues, have incurred significant expenses and have sustained losses. Consequently, our operations are subject to all the risks inherent in the establishment of a new business enterprise.

On November 3, 2015, the Company issued a press release reporting the U.S. Food and Drug Administration ("FDA") has granted the Company's de novo request for the INVOcell to allow the marketing, sale and use in the United States.

On November 12, 2018, the Company entered into a Distribution Agreement with Ferring pursuant to which, among other things, the Company granted to Ferring an exclusive license in the United States with rights to sublicense under patents related to the Company's proprietary intravaginal culture device known as INVOcell™, together with the retention device and any other applicable accessories to market, promote, distribute and sell the Licensed Product with respect to all therapeutic, prophylactic and diagnostic uses of medical devices or pharmaceutical products involving reproductive technology (including infertility treatment) in humans (the "Field"). Ferring is responsible, at its own cost, for all commercialization activities for the Licensed Product in the Field in the United States. The Company does retain a limited exception to the exclusive license granted to Ferring allowing the Company, subject to certain restrictions, to establish up to five clinics that will commercialize INVO cycles in the United States. The Company retains all commercialization rights for the Licensed Product outside of the United States.

(B) Basis of Presentation *(Share Exchange and Corporate Structure)*

On December 5, 2008, the Company completed a share exchange with Emy's Salsa Aji Distribution Company, Inc. ("Emy's"), a publicly registered shell corporation with no significant assets or operations. Emy's was incorporated on July 11, 2005, under the laws of the State of Nevada under the name Certiorari Corp. In connection with the share exchange, INVO Bioscience became Emy's wholly-owned subsidiary and the INVO Bioscience shareholders acquired control of Emy's.

The Company accounted for the transaction as a recapitalization and the Company is the surviving entity. In connection with the share exchange, Emy's shareholders retained 14,937,500 shares. Effective with the Agreement, all previously outstanding shares of Common Stock owned by the Company's shareholders were exchanged for an aggregate of 38,307,500 shares of Emy's common stock. Effective with the Agreement, Emy's changed its name to INVO Bioscience, Inc.

All references to "Common Stock," "share" and "per share" amounts have been retroactively restated to reflect the exchange ratio of 357.0197 shares of INVO Bioscience Common Stock for one share of Emy's common stock outstanding immediately prior to the merger as if the exchange had taken place as of the beginning of the earliest period presented.

The accompanying consolidated financial statements present the historical financial condition, results of operations and cash flows of the Company prior to the merger with Emys. The accompanying consolidated financial statements present on a consolidated basis the accounts of the Company and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation.

(C) Use of Estimates

In preparing financial statements in conformity with generally accepted accounting principles, management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and revenues and expenses during the reported period. Actual results could differ from those estimates.

(D) Cash and Cash Equivalents

The Company considers all highly liquid temporary cash investments with an original maturity of three months or less to be cash equivalents. The Company had the amounts of cash and cash equivalents on its balance sheets as of December 31, 2018 and 2017 of $212,243 and $25,759, respectively.

(E) Inventory

Inventories consist of work in process (WIP) and finished products and are stated at the lower of cost or market; using the first-in, first-out (FIFO) method as a cost flow convention.

(F) Property and Equipment

The Company records property and equipment at cost. Depreciation and amortization are provided using the straight-line method over the estimated economic lives of the assets, which are from 3 to 7 years. The Company capitalizes the expenditures for major renewals and improvements that extend the useful lives of property and equipment. Expenditures for maintenance and repairs are charged to expense as incurred. The Company reviews the carrying value of long-lived assets for impairment at least annually or whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of long-lived assets is measured by a comparison of its carrying amount to the undiscounted cash flows that the asset or asset group is expected to generate. If such assets are considered impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the property, if any, exceeds its fair market value.

(G) Stock Based Compensation

The Company accounts for stock-based compensation under the provisions of Accounting Standards Codification subtopic 718-10, Compensation ("ASC 718-10"). This statement requires the Company to measure the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost is recognized over the period in which the employee is required to provide service in exchange for the award, which is usually the vesting period.

(H) Loss Per Share

Basic loss per share calculations are computed by dividing income (loss) available to common shareholders by the weighted-average number of common shares outstanding. Diluted earnings per share is computed similar to basic earnings per share except that the denominator is increased to include securities or other contracts to issue common stock that would have been outstanding if the potential common shares had been issued and if the additional common shares were dilutive. The Company's diluted loss per share is the same as the basic loss per share for the years ended December 31, 2018 and 2017, as the inclusion of any potential shares would have had an anti-dilutive effect due to the Company generating a loss.

	Twelve Months Ended December 31,	
	2018	**2017**
Loss to common shareholders (Numerator)	$ (3,076,091)	$ (702,163)
Basic and diluted weighted-average number of common shares outstanding (Denominator)	147,333,051	141,305,050

The Company has excluded the following dilutive securities from the calculation of fully-diluted shares outstanding because the result would have been anti-dilutive:

	Twelve Months Ended December 31,	
	2018	2017
Effect of dilutive common stock equivalents:		
Convertible notes and interest	6,020,200	3,391,300
Total	6,020,200	3,391,300

(I) Fair Value of Financial Instruments

ASC 825-10-50, "Disclosures about Fair Value of Financial Instruments," (formerly SFAS No. 107) requires disclosure of the fair value of certain financial instruments. The carrying value of cash and cash equivalents, accounts payable and borrowings, as reflected in the balance sheets, approximate fair value because of the short-term maturity of these instruments.

Effective January 1, 2008, the Company adopted ASC 820-10, "Fair Value Measurements" (SFAS 157), which provides a framework for measuring fair value under GAAP. ASC 820-10 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC 820-10 requires that valuation techniques maximize the use of observable inputs and minimize the use of unobservable inputs.

(J) Income Taxes

The Company accounts for income taxes under the ASC 740-10-05, "Accounting for Income Taxes" (SFAS 109). Under ASC 740-10, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Under ASC 740-10, the effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

On December 22, 2017, the Tax Cuts and Jobs Act (TCJA) was signed into law by the President of the United States. TCJA is a tax reform act that among other things, reduced corporate tax rates to 21 percent effective January 1, 2018. FASB ASC 740, *Income Taxes*, requires deferred tax assets and liabilities to be adjusted for the effect of a change in tax laws or rates in the year of enactment, which is the year in which the change was signed into law. Accordingly, the Company adjusted its deferred tax assets and liabilities at December 31, 2017, using the new corporate tax rate of 21 percent. See Note 10.

(K) Business Segments

The Company operates in one segment and therefore segment information is not presented.

(L) Concentration of Credit Risk

Cash includes amounts deposited in financial institutions in excess of insurable Federal Deposit Insurance Corporation (FDIC) limits. As of December 31, 2018, the Company had no cash balances in excess of FDIC limits.

(M) Revenue Recognition

The Company will recognize revenue on arrangements in accordance with ASC 606 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services.

(N) Long- Lived Assets

Long-lived assets and certain identifiable assets related to those assets are periodically reviewed for impairment whenever circumstances and situations change such that there is an indication that the carrying amounts may not be recoverable. If the non-discounted future cash flows of the enterprise are less than their carrying amount, their carrying amounts are reduced to the fair value and an impairment loss recognized. There was no impairment recorded from January 5, 2007 (inception) to December 31, 2018.

(O) Reclassifications

Certain reclassifications have been made in prior year's financial statements to conform to classifications used in the current year.

(P) Recent Accounting Pronouncements

In May 2014, the FASB issued ASC 606, Revenue from Contracts with Customers ("ASC 606"). The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. The standard is effective for annual periods beginning after December 15, 2017, and interim periods therein.

ASU 2014-09 supersedes existing guidance on revenue recognition with a five-step model for recognizing and measuring revenue from contracts with customers. The objective of the new standard is to provide a single, comprehensive revenue recognition model for all contracts with customers to improve comparability within industries, across industries, and across capital markets. The underlying principle is that an entity will recognize revenue to depict the transfer of goods or services to customers at an amount that the entity expects to be entitled to in exchange for those goods or services. The guidance also requires a number of disclosures regarding the nature, amount, timing, and uncertainty of revenue and the related cash flows. The guidance can be applied retrospectively to each prior reporting period presented (full retrospective method) or retrospectively with a cumulative effect adjustment to retained earnings for initial application of the guidance at the date of initial adoption (modified retrospective method). The Company adopted the new standard effective January 1, 2018 using the modified retrospective method applied to those contracts that were not completed or substantially completed as of January 1, 2018. The timing and measurement of revenue recognition under the new standard is not materially different than under the old standard. The adoption of the new standard did not have an impact on the Company's consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, *Improvements to Employee Share-Based Payment Accounting*, which intends to simplify several aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, a choice to recognize gross stock compensation expense with actual forfeitures recognized as they occur, as well as certain classifications on the statement of cash flows. The Company adopted this ASU in Fiscal 2018 and it did not have a material impact on the Company's consolidated financial position, results of operations or cash flows.

In August 2016, the FASB issued ASU 2016-15, Statement of Cash Flows (Topic 230) ("ASU 2016-15"). The updated standard addresses eight specific cash flow issues with the objective of reducing diversity in practice. ASU 2016-15 is effective for public business entities for annual reporting periods beginning after December 15, 2017, including interim periods within those annual reporting periods. Early adoption is permitted. The Company adopted ASU 2016-15 as of January 1, 2018. The adoption of ASU 2016-15 did not have an impact on the Company's consolidated financial statements.

In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230) ("ASU 2016-18"). The updated standard requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 is effective for public business entities for annual reporting periods beginning after December 15, 2017, including interim periods within those annual reporting periods. The Company adopted ASU 2016-18 as of January 1, 2018. The adoption of ASU 2016-18 did not have a material effect on the Company's consolidated financial statements.

In May 2017, the FASB issued ASU 2017-09, Compensation – Stock Compensation (Topic 718) ("ASU 2017-09"). The updated standard clarifies when an entity must apply modification accounting to changes in the terms or conditions of a share-based payment award. ASU 2017-09 is effective for public business entities for annual reporting periods beginning after December 15, 2017, including interim periods within those annual reporting periods. Early adoption is permitted. The Company adopted ASU 2017-09 as of January 1, 2018. The adoption of ASU 2017-09 did not have a material effect on the Company's consolidated financial statements.

In February 2016, FASB issued ASU 2016-02, Leases ("ASU 2016-02"). The new standard establishes a right-of-use ("ROU") model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company is currently evaluating the impact of its pending adoption of ASU 2016-02 on its consolidated financial statements.

In July 2017, FASB issued ASU 2017-11 (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception ("ASU 2017-11"). The new standard simplifies the accounting for certain financial instruments with down round features. Part I of ASU 2017-11 changes the classification analysis of certain equity-linked financial instruments, such as warrants and embedded conversion features, such that a down round feature is disregarded when assessing whether the instrument is indexed to an entity's own stock under Subtopic 815-40, Contracts in Entity's Own Equity. As a result, a down round feature, by itself, no longer requires an instrument to be re-measured at fair value through earnings each period, although all other aspects of the indexation guidance under Subtopic 815-40 continue to apply. Part II of ASU 2017-11 re-characterizes the indefinite deferral of certain provisions of Topic 480, Distinguishing Liabilities from Equity, (currently presented as pending content in the Codification) as a scope exception. No change in practice is expected as a result of these amendments. The new standard is effective for fiscal years beginning after December 15, 2018, early adoption is permitted. The amendments in Part II have no accounting impact and therefore do not have an associated effective date. The Company decided to early adopt this ASU 2017-11 and applied it to the convertible notes it issued during the quarter which are reflected in this Form 10Q.

Management was not aware of any accounting issued, but not yet effective accounting standards, if currently adopted would have material effect on the consolidated financial statements.

NOTE 2 GOING CONCERN

The Company commenced operations in December 2008. During the year ended December 31, 2018, the Company had a net loss of $3,076,000 and cash used in operations of $653,000. At December 31, 2018, the Company had a working capital deficiency of $2,770,000 and a stockholder deficiency of $2,724,000. This raises substantial doubt about its ability to continue as a going concern. The financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern. The ability of the Company to continue as a going concern is dependent on the Company's ability to raise additional capital and implement its business plan.

NOTE 3 INVENTORY

The Company had inventory in the following amounts:

	December 31, 2018	December 31, 2017
Work in Process	$ 30,689	$ 24,357
Finished Goods	12,824	34,522
Total Inventory	$ 43,513	$ 58,879

NOTE 4 PROPERTY AND EQUIPMENT

The estimated useful lives and accumulated depreciation for furniture, equipment and software are as follows:

	Estimated Useful Life
Molds	3 to 7 years

	December 31, 2018	December 31, 2017
Manufacturing Equipment- Molds	$ 70,363	$ 50,963
Accumulated Depreciation	(35,917)	(35,263)
	$ 34,446	$ 15,700

The Company recorded $654 and $0 depreciation expense in 2018 and 2017 as its earlier equipment was fully depreciated.

NOTE 5 PATENTS

The Company capitalizes the initial expense related to establishing the patent by country and then amortizes the expense over the life of the patent, typically 20 years. It then expenses annual filing fees to maintain the patents. The Company regularly reviews the value of the patent in the market place in proportion to the expense it must spend to maintain the patent.
The Company has recorded the following patent costs:

	December 31, 2018	December 31, 2017
Total Patents	$ 77,743	$ 77,743
Accumulated Amortization	(65,951)	(61,415)
Patent costs, net	$ 11,792	$ 16,328

The Company recorded amortization expense as follows:

Twelve Months Ended December 31,	
2018	2017
$ 4,536	$ 2,810

In 2011, the decision was made to not to pay the renewal fees and expedite the amortization of the original patent which expired in 2012. It was also decided to not spend its limited funds in defending the INVO Block patent as it only has value to the Company. The Company continues to pay the annual renewal fees on its active patents.

Estimated amortization expense as of December 31, 2018 is as follows:

Years ended December 31,	
2019	$ 4,536
2020	1,809
2021	1,809
2022	1,809
2023 and thereafter	1,829
Total	$ 11,792

NOTE 6 CONVERTIBLE NOTES AND NOTES PAYABLE

Convertible Notes - Bridge Notes

During 2009, the Company issued senior secured convertible notes ("Bridge Notes") payable to investors in the aggregate amount of $545,000. The Bridge Notes carry interest rates ranging between 10-12% and were due in full one year from the date of issuance and are past due. Both the Bridge Notes and the accrued interest thereon are convertible into Restricted Common Stock of the Company at a conversion price of $0.10 per share (the "Original Conversion Price"). If the Company were to issue any new shares of common stock within 24 months of the date of the Bridge Notes at a price below the Original Conversion Price, then the conversion price of the Bridge Notes would be adjusted to reflect the new lower price. In addition to the Bridge Notes, the Company issued warrants to purchase 5,750,000 shares of the Company's Common Stock at a price of $0.20 per share as of the date of this filing. All the warrants have expired. The Company valued the conversion feature of the Bridge Notes and the warrants issued via the Black-Scholes valuation method. The total fair value calculated for the conversion feature was $1,473,710; $151,826 was allocated to discount on the Bridge Notes, and $1,341,884 was charged to operations. The total fair value calculated for the warrants was $1,719,666; $393,174 was allocated to discount on the Bridge Notes, and $1,326,492 was charged to operations. The aggregate discount on the Bridge Notes for the conversion feature and the warrants was $545,000, and the aggregate amount charged to operations was $2,668,371 which was recorded as a derivative liability on the Company's consolidated balance sheet.

From November 2009 through May 2015 $535,000 of the principal of the Bridge Notes were converted into shares of Restricted Common Stock.

In March 2017, the Company converted the last Bridge Note in the amount of $10,000 and accrued interest into shares of common stock. The Company negotiated this conversion at a price lower than the conversion price stated in the original Bridge Note documents because the Bridge Note was past due. This conversion was treated as a restructure of debt on the Company's financial statements for the six months ended June 30, 2017. $10,000 of the Bridge Notes and accrued interest were converted into 341,000 shares of restricted common stock resulting in a loss on debt settlement in the amount of $40,869.
The principal balances of the Convertible Notes was $0 for both 2018 and 2017, respectively. The last note was converted in Q1 2017. The related interest for the twelve months ended December 31, 2018 and 2017 was $0.

Notes Payable

In August 2016, INVO Bioscience converted a long time vendor's outstanding accounts payable balance of $131,722 into a three (3) year 5% notes payable. The note provides for interest only payments on the first and second anniversaries of the note. The note is payable in full along with any outstanding accrued interest on the third anniversary. The Company has the right to prepay the note at any time without a premium or penalty. The interest on this note for the years ended December 31, 2018 and 2017 was $6,586 and $9,586, respectively.

2018 Convertible Notes Payable

In April and May 2018, the Company issued convertible notes (the "2018 Convertible Notes") payable to investors in the aggregate principal amount of $895,000. The 2018 Convertible Notes accrue interest at the rate of 9% per annum which is paid in stock. 2018 Convertible Notes with an aggregate principal amount of $550,000 are due on January 30, 2021, and 2018 Convertible Notes with an aggregate principal amount of $345,000 are due on March 31, 2021. The notes are convertible into shares of common stock at a price of $0.20 per share, provided, that if the Company completes a subsequent equity financing, the holders of the 2018 Convertible Notes can elect to convert the notes in shares of our common stock at a price equal to 75% of the price paid per share in such subsequent equity financing. During the fourth quarter of 2018, three note holders converted their notes with a value of $200,000 into 1,055,415 shares of common stock.

The Company calculated a beneficial conversion feature of the 2018 Convertible Notes based on ASU 17-11 in the form of a discount of $895,000; $366,126 of this amount was amortized to interest expense during the twelve months ended December 31, 2018, based on the three year term of the notes. In addition $53,564 of interest was expensed in the year ended December 31, 2018.

NOTE 7 OTHER RELATED PARTY TRANSACTIONS

On September 18, 2008, the Company entered into a related party transaction with Dr. Claude Ranoux. Dr. Ranoux was then the President, Director and Chief Scientific Officer of the Company; as of the date of this filing he is a Director. Dr. Ranoux had loaned funds to the Company to sustain its operations since January 5, 2007 (inception). Dr. Ranoux's total original cumulative investment as of December 31, 2008 was $96,462, as of December 31, 2017 and 2016 it is $21,888 ("the Principal Amount") in INVO Bioscience. On March 26, 2009, the Company and Dr. Ranoux agreed to re-write the agreement to a non-convertible note payable bearing interest at 5% per annum, the term of the note had been extended, and has been extended a couple of additional times, the current repayment date is October 31, 2018. The Company and Dr. Ranoux can jointly decide to repay the loan earlier without prepayment penalties. During the twelve months ended December 31, 2018 the outstanding balance of $21,888 was paid in full including all interest due, in 2017, $0 was repaid on the principal of the loan.

On March 5, 2009, the Company entered into a related party transaction with Kathleen Karloff, the Chief Executive Officer and a Director of the Company. Ms. Karloff provided a short-term loan in the amount of $75,000 bearing interest at 5% per annum to the Company to fund operations. In May 2009, Ms. Karloff loaned to the Company an additional $13,000, making her total cumulative loan $88,000 as of December 31, 2011. This note was due on September 15, 2009, which has since been extended a few times to its current date of October 31, 2018. During the twelve months ended December 31, 2014, Ms. Karloff loaned the Company an additional $66,000 at an interest rate of 0% by entering into a note payable agreement in satisfaction of expenses incurred by her for amounts previously advanced to the Company. This note currently has the same expiration date as the others which is October 31, 2018. During the twelve months ended December 31, 2018 $91,257 was paid against the principal of the loan, in 2017, $0 was repaid on the principal of the loan. The principal balances of the loan was $62,743 and $154,000 as of December 31 2018 and 2017 respectively. The related interest for the twelve months ended December 31, 2018 and 2017 was $15,278 and $4,400 respectively.

In December 2009, James Bowdring, the brother of Director Robert Bowdring invested $100,000 acquiring 666,667 shares of restricted common stock. In April 2011, the Company issued a new short term convertible note ("Q211 Note") payable to James Bowdring in the amount of $50,000. The Note carries a 10% interest rate. The note has a current balance of $25,000. The Q211 Note is convertible into Common Stock of the Company at a conversion price of $0.03 per share, subject to adjustments.

In November 2011, the Company issued a new convertible note ("Q411 Note") payable to James Bowdring in the amount of $10,000. The Q411 Note carries a 10% interest rate. The Q411 Note is convertible into Common Stock of the Company at a conversion price of $0.01 per share, subject to adjustments.

In May 2018, James Bowdring and his children participated in the "2018 Convertible Notes" offerings in the aggregate principal amount of $40,000. The 2018 Convertible Notes accrue interest at the rate of 9% per annum which is paid in stock. These Notes are due on March 31, 2021. The notes are convertible into shares of common stock at a price of $0.20 per share, provided, that if the Company completes a subsequent equity financing, the holders of the 2018 Convertible Notes can elect to convert the notes in shares of our common stock at a price equal to 75% of the price paid per share in such subsequent equity financing.

The Company has been renting its corporate office from Forty Four Realty Trust which is owned by James Bowdring, the brother of Director, Robert Bowdring since November 2012. It is a month to month rental arrangement for less than the going fair market real estate rental rate. The rent expense paid for the twelve months ended December 31, 2018 and 2017 was $5,600 and $4,400 respectively. In addition the Company purchases stationary supplies and marketing items at discounted rates from Superior Printing & Promotions which is also owned by James Bowdring and is in the same building as our corporate office. INVO Bioscience spent $2,130 and $4,100 with Superior during 2018 and 2017, respectively.

Principal balances of the Related Party loans were as follows:

	December 31, 2018	December 31, 2017
Claude Ranoux Note	$ -	$ 21,888
James Bowdring Family - 2011 Notes	35,000	35,000
James Bowdring Family – 2018 Convertible Notes	40,000	-
Kathleen Karloff Note	62,743	154,000
Less discount	(30,913)	-
Total, net of discount	$ 106,830	$ 210,888

Interest expense on the Related Party loans was $21,976 and $11,543 for the years ended December 31, 2018 and 2017, respectively.

Accounts payable and accrued liabilities balances include expenses reports for Ms. Karloff, and Mr. Bowdring for expenses they paid for personally related to travel or normal business expenses and are represented in the following table:

	December 31,	
	2018	2017
Accounts payable and accrued liabilities	$ 1,700	$ 38,000

During the nine months ended September 30, 2018, the Company sold 150,000 shares of common stock at a price of $0.20 per share for proceeds of $30,000 to Charles Mulrey and family, the brother-in-law of Robert J. Bowdring, Director & Acting Chief Financial Officer as part of the recent financing.

During the second quarter of 2018, INVO Bioscience settled a commitment it had with one of its Directors, Dr. Kevin Doody for the services he and his team performed prior to and following INVOcell's FDA clearance related to clinical guidance and support. Dr. Doody and his team performed clinical studies and provided papers, lectures and discussions with regulatory bodies and key opinion leaders in the industry. The Company believes without Dr. Doody's services and support during his tenure the Company would not be where it is today. The Company issued Dr. Doody 3 million shares of our common stock with a fair value of $1,530,000.

NOTE 8 STOCKHOLDERS' EQUITY

Twelve Months Ended December 31, 2018

In January and March 2018, pursuant to Section 4(a)(2) of the Securities Act, the Company sold 260,000 shares of common stock to accredited investors in a private placement for cash of $47,000.

In January 2018, pursuant to Section 4(a)(2) of the Securities Act, the Company issued 1,200,000 shares of common stock with a fair value of $138,000 to management and board members.

In January and March 2018, pursuant to Section 4(a)(2) of the Securities Act, the Company issued 352,326 shares of common stock with a fair value of $43,664 to service providers.

In April and May 2018, pursuant to Section 4(a)(2) of the Securities Act, the Company issued 340,000 shares of common stock with a fair value of $174,800 to service providers.

In May 2018, pursuant to Section 4(a)(2) of the Securities Act, the Company sold 150,000 shares of common stock to accredited investors who are family members of Robert J Bowdring, a Board Member in a private placement for cash of $30,000.

In May 2018, pursuant to Section 4(a)(2) of the Securities Act, the Company issued 3,020,000 shares of common stock with a fair value of $1,540,000 to a board member, Dr. Kevin Doody for services previously provided to the Company.

In October 2018, pursuant to Section 4(a)(2) of the Securities Act, the Company issued 4,895,076 shares of common stock with a fair value of $1,914,831 to employees and service providers.

In November 2018, pursuant to Section 4(a)(2) of the Securities Act, the Company issued 262,080 shares of common stock for conversion of notes payable and accrued interest in the amount of $52,416.

In December 2018, pursuant to Section 4(a)(2) of the Securities Act, the Company issued 793,335 shares of common stock for conversion of notes payable and accrued interest in the amount of $158,667.

In December 2018, pursuant to Section 4(a)(2) of the Securities Act, the Company issued 887,306 shares of common stock with a fair value of $349,602 to employees and service providers.

Twelve Months Ended December 31, 2017

In March 2017, pursuant to Section 4(2) of the Securities Act, the Company issued 196,000 shares of restricted common stock with a fair value of $59,242 to service providers.

In March 2017, pursuant to Section 4(2) of the Securities Act, the Company negotiated the conversion of $10,000 of past due Bridge Notes and accrued interest into 341,000 shares of restricted common stock resulting in a loss on debt settlement in the amount of $40,869.

In April 2017, pursuant to Section 4(2) of the Securities Act, the Company issued 51,750 shares of restricted common stock with a fair value of $17,201 to service providers.

In June 2017, pursuant to Section 4(2) of the Securities Act, the Company issued 99,412 shares of restricted common stock with a fair value of $30,898 to service providers.

In September 2017, pursuant to Section 4(2) of the Securities Act, the Company issued 133,960 shares of restricted common stock with a fair value of $28,576 to service providers.

In September 2017, pursuant to Section 4(2) of the Securities Act, the Company issued 262,500 shares of restricted common stock for cash proceeds of $44,625.

In November 2017, pursuant to Section 4(2) of the Securities Act, the Company issued 395,550 shares of restricted common stock with a fair value of $79,215 to service providers.

In November 2017, pursuant to Section 4(2) of the Securities Act, the Company issued 55,556 shares of restricted common stock for cash proceeds of $10,000.

NOTE 9 STOCK OPTIONS AND WARRANTS

Stock Options

As of December 31, 2018 and 2017, the Company does not have any outstanding or committed and unissued stock options.

Warrants

As of December 31, 2018 and 2017, the Company does not have any outstanding or committed and unissued warrants.

NOTE 10 INCOME TAXES

The Company has adopted ASC 740-10, which requires the recognition of deferred tax liabilities and assets for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax liabilities and assets are determined based on the difference between financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse.

The Company's total deferred tax liabilities, deferred tax assets, and deferred tax asset valuation allowances are as of December 31 are as follows:

	December 31, 2018	December 31, 2017
Total deferred tax assets	$ 4,124,000	$ 3,730,000
Less valuation allowance	(4,124,000)	(3,730,000)
Total deferred tax liabilities	-	-
Net deferred tax asset (liability)	$ -	$ -

Those amounts have been presented in the company's financial statements as of December 31, as follows:

	December 31,	
	2018	2017
Deferred tax asset	$ -	$ -
Deferred tax liability	-	-
Net deferred tax asset (liability)	$ -	$ -

The company has a loss carry forward of $9.6 million that may be offset against future taxable income.

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cut and Jobs Act (the "Tax Act"). The Tax Act establishes new tax laws that affects 2018 and future years, including a reduction in the U.S. federal corporate income tax rate to 21%, effective January 1, 2018. For certain deferred tax assets and deferred tax liabilities, we have recorded a provisional decrease of $1,680,000, with a corresponding net adjustment to valuation allowance of $1,680,000 as of December 31, 2017.

Realization of deferred tax assets is dependent on future earnings, if any, the timing and amount of which is uncertain. Those amounts are therefore presented on the Company's balance sheets as a non-current asset. Utilization of the net operating loss carry forwards may be subject to substantial annual limitations, which may result in the expiration of net operating loss carry forwards before utilization.

NOTE 11 COMMITMENTS AND CONTINGENCIES

A) Operating Leases

In November 2012, INVO Bioscience entered into a below market, month to month rental agreement with Forty Four Realty Trust with for the space it requires. Forty Four Realty Trust is owned by investor James Bowdring, the brother of Director Robert Bowdring.

B) Litigation

INVO Bioscience, Inc., and two of its directors have been, since 2010, defending litigation brought by investors in an alleged predecessor of INVO Bioscience. On March 24, 2010, INVO Bioscience, Inc. and its corporate affiliate, Bio X Cell, Inc., Claude Ranoux, and Kathleen Karloff were served an Amended Complaint, the original of which was filed on December 31, 2009 at the Suffolk Superior Court Business Litigation Session by two terminated employees of Medelle Corporation (also named as a co-defendant but no longer active), who are also attorneys, and a former investor in and creditor of Medelle. These plaintiffs allege various claims of wrongdoing relating to the sale of assets of Medelle to Dr. Ranoux. Plaintiffs claim that Dr. Ranoux, Ms. Karloff, and Medelle (and therefore INVO Bioscience as an alleged successor corporation) violated alleged duties owed to plaintiffs in connection with the sale. Separate claims were also alleged against INVO Bioscience.

Dr. Ranoux, Ms. Karloff, and INVO Bioscience have challenged these allegations, which they believe are baseless. The transfer of the assets of Medelle was professionally handled by an independent third party, after approval by the Medelle Board of Directors, representing a majority of its shareholders. Medelle's Board voted to proceed with an assignment for the benefit of creditors (AFBC) and gave complete authority to the President & CEO at that time (neither Dr. Ranoux nor Ms. Karloff) to work with the third-party assignee and to get the best possible price for those assets. The third party was responsible for notifying all the appropriate parties and for filing notices in various professional publications and newspapers of Medelle's intention to sell its assets. The third party also contacted numerous large medical device and bio-pharma companies to learn if they would be interested in acquiring the assets. After a private sale was deemed unlikely, the assignee of the assets elected to proceed with a sealed-bid auction of the assets. On the day of the auction, Dr. Ranoux submitted the only bid and was awarded the assets, upon full payment.

During 2010, Dr. Ranoux, Ms. Karloff, and INVO Bioscience filed Motions to Dismiss as to all claims, pursuant to M.R.Civ. P. 12(b)(6). In a written Decision rendered on November 12, 2010, the judge dismissed all claims against INVO, Bio X Cell, and Ms. Karloff, and also dismissed the claims against Dr. Ranoux alleging civil conspiracy and breach of M.G.L. c. 93A. The judge denied Dr. Ranoux's motion to dismiss the remaining breach of fiduciary duty and fraud claims. The plaintiffs allege in their Amended Complaint that Dr. Ranoux committed fraud by failing to inform them of the details of the Medelle auction.

The claims against Dr. Ranoux that survived the November 2010 dismissal order were submitted to binding arbitration. On February 15, 2013, the mutually-agreed arbitrator ruled in favor of Dr. Ranoux. The award held that Dr. Ranoux did not withhold information about the auction of Medelle's assets and expressed doubt that the plaintiffs would have invested the resources necessary to make a beneficial use of the assets. The arbitrator's award then was confirmed by the Superior Court on August 21, 2013. The Superior Court's confirmation of the award was affirmed on appeal on October 20, 2013 by the Massachusetts Appeals Court. The Massachusetts Supreme Judicial Court then denied further appellate review.

On October 18, 2016, following motions and argument, the Superior Court issued a memorandum of decision and order denying plaintiffs' motion for entry of default judgment and assessment of damages against Medelle and allowed the motion of INVO Bioscience, Bio X Cell, and Ms. Karloff for entry of final judgment of dismissal. The foregoing order was converted to a final judgment dismissing all claims against all defendants and entered on the docket on October 27, 2016.

On November 28, 2016, plaintiffs filed an amended notice of appeal from the Superior Court's decision of October 17, 2016 and the subsequent judgment entered on October 27, 2016. The appeal further challenges the order of dismissal from November, 2010. Plaintiffs did not appeal from the dismissal of the claims against Ms. Karloff, so the judgment in her favor is now final, leaving claims against INVO Bioscience, Bio X Cell, Medelle, and Dr. Ranoux.

INVO Bioscience and Bio X Cell intend a vigorous opposition to the current appeal, consistent with their previous positions that no breach of duty occurred in the sale of Medelle's assets. It is assumed that Dr. Ranoux will oppose the appeal as well.

Outside of the above-mentioned litigation, neither INVO Bioscience nor Bio X Cell, our wholly-owned subsidiary, either directly or indirectly, are involved in any lawsuit outside the ordinary course of business, the disposition of which would have a material effect upon either our results of operation, financial position, or cash flows.

C) Employee Agreements

The Company had employment agreements for officers, executives and employees of the Company in place but they have expired. The Company in the in the process of drafting new agreements for all of its key personnel.

D) Consulting Agreements

The Company has a verbal agreement beginning in March, 2013 with its former CFO, Robert Bowdring, who is currently a Director, to assist where necessary in the financial and administrative areas of the Company for compensation to be equivalent to the others working in the organization.

NOTE 12 CONTRACTS WITH CUSTOMERS

We have adopted ASC 606, *Revenue from Contracts with Customers* effective January 1, 2018 using the modified retrospective method applied to those contracts which were not substantially completed as of January 1, 2018. These standards provide guidance on recognizing revenue, including a five-step model to determine when revenue recognition is appropriate. The standard requires that an entity recognize revenue to depict the transfer of control of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. Revenues for 2018 are reported under ASC 606, while prior period amounts are not adjusted and continue to be reported under ASC 605, *Revenue Recognition*.

We routinely enter into agreements with customers that include general commercial terms and conditions, notification requirements for price increases, shipping terms and in most cases prices for the products that we offer. However, these agreements do not obligate us to provide goods to the customer and there is no consideration promised to us at the onset of these arrangements. For customers without separate agreements, we have a standard list price established by geography and by currency for all products and our invoices contain standard terms and conditions that are applicable to those customers where a separate agreement is not controlling. Our performance obligations are established when a customer submits a purchase order or e-mail notification (in writing, electronically or verbally) for goods, and we accept the order. We identify performance obligations as the delivery of the requested product(s) in appropriate quantities and to the location specified in the customer's e-mail/or purchase order. We generally recognize revenue upon the satisfaction of these criteria when control of the product has been transferred to the customer at which time we have an unconditional right to receive payment. Our prices are fixed and are not affected by contingent events that could impact the transaction price. We do not offer price concessions and do not accept payment that is less than the price stated when we accept the purchase order, except in rare credit related circumstances. We do not have any material performance obligations where we are acting as an agent for another entity.

Revenues for products, including: INVOcell®, INVO ™ Retention System, and INVO Microscope Holding Block are typically recognized at the time the product is shipped, at which time the title passes to the customer, and there are no further performance obligations. Revenues from consignment are recognized when the medical device is shipped from the Consignor to the customer.

Sources of Revenue

We have identified the following revenues disaggregated by revenue source:

1. Domestic Physicians – direct sales of products.
2. Domestic Distributors – direct sales of products
3. International Distributors – direct sales of products.

For the year ended December 31, 2018 the primary source of our revenue was from Domestic Physicians, the Company had $61,000 in shipments to its Domestic Distributor and 2017 the source of revenue was only from Domestic Physicians.

Contract Balances

We incur agreement obligations on general customer purchase orders and e-mails that have been accepted but unfulfilled. Due to the short duration of time between order acceptance and delivery of the related product, we have determined that the balance related to these obligations is generally immaterial at any point in time. We monitor the value of orders accepted but unfulfilled at the close of each reporting period to determine if disclosure is appropriate.

Warranty

Our general product warranties do not extend beyond an assurance that the product delivered will be consistent with stated specifications and do not include separate performance obligations.

Significant Judgments in the Application of the Guidance in ASC 606

There are no significant judgments associated with the satisfaction of our performance obligations. We generally satisfy performance obligations upon delivery of the product to the customer. This is consistent with the time in which the customer obtains control of the products. Therefore the value of unsatisfied performance obligations at the end of any reporting period is generally immaterial. We consider variable consideration in establishing the transaction price. Forms of variable consideration applicable to our arrangements include sales returns, rebates, volume based bonuses, and prompt pay discounts. We use historical information along with an analysis of the expected value to properly calculate and to consider the need to constrain estimates of variable consideration. Such amounts are included as a reduction to revenue from the sale of products in the periods in which the related revenue is recognized and adjusted in future periods as necessary.

Commissions and Contract Costs

We do not use or offer sales commissions of any type at this time. We generally do not incur incremental charges associated with securing agreements with customers which would require capitalization and recovery over the life of the agreement.

Practical Expedients

Our payment terms for sales direct to customers and distributors are substantially less than the one year collection period that falls within the practical expedient in determination of whether a significant financing component exists.

Shipping and Handling Charges

Fees charged to customers for shipping and handling of products are included as an offset to the costs for shipping and handling of products included as a component of cost of products.

Taxes Collected from Customers

As our products are used in another service and are exempt, to this point we have not collected taxes. If we were to collect taxes they would be on the value of transaction revenue and would be excluded from product revenues and cost of sales and would be accrued in current liabilities until remitted to governmental authorities.

Effective Date and Transition Disclosures

Adoption of the new standards related to revenue recognition did not have a material impact on our consolidated financial statements, and is not expected to have a material impact in future periods.

NOTE 13 SUBSEQUENT EVENTS

On January 14, 2019, the Company consummated the transactions contemplated by its previously reported Distribution Agreement with Ferring International Center S.A. (“Ferring”), dated November 12, 2018.

At the closing, the Company received its initial $5,000,000 license fee. Pursuant to the Distribution Agreement, among other things, the Company granted to Ferring an exclusive license in the United States with rights to sublicense under patents related to the Company’s proprietary intravaginal culture device known as INVOcell™, together with the retention device and any other applicable accessories to market, promote, distribute and sell the Licensed Product with respect to all therapeutic, prophylactic and diagnostic uses of medical devices or pharmaceutical products involving reproductive technology (including infertility treatment) in humans. Ferring is responsible, at its own cost, for all commercialization activities for the Licensed Product in humans in the U.S. The Company does retain a limited exception to the exclusive license granted to Ferring allowing the Company, subject to certain restrictions, to establish up to five clinics that will commercialize INVO cycles in the U.S.. The Company retains all commercialization rights for the Licensed Product outside of the United States.

In January 2019 we hired Mr. Michael Campbell as COO and VP of Business Development. Mr. Campbell has been on our Board of Directors for the past sixteen months. He has over 20 years in the infertility market most recently with Cooper Surgical as the VP of the IVF America division and previously in the position of VP of the international IVF market.

In January 2019, pursuant to Section 4(a)(2) of the Securities Act, the Company issued 60,000 shares of restricted common stock with a fair value of $26,600 to service providers for services performed.

In February 2019, pursuant to Section 4(a)(2) of the Securities Act, the Company issued 268,615 shares of restricted common stock with a fair value of $53,168 in connection with the conversion of a note payable and accrued interest.

In March 2019 the Company decided to change its stock transfer agent from Island Stock Transfer Company to Transfer Online, Inc. https://www.transferonline.com/ as Island is no longer able to meet the needs of INVO Bioscience.

43,397,049 Shares of

Common Stock

PRELIMINARY PROSPECTUS

July 29, 2019

PART II - INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 13. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION

The following table sets forth an itemization of various expenses, all of which we will pay, in connection with the sale and distribution of the securities being registered. All of the amounts shown are estimates, except the Securities and Exchange Commission registration fee.

Securities and Exchange Commission Registration Fee	$	1,788
Accounting Fees and Expenses		10,000
Legal Fees and Expenses		100,000
Transfer agent fees		4,000
Miscellaneous		5,000
Total	$	120,788

ITEM 14. INDEMNIFICATION OF DIRECTORS AND OFFICERS

We are a Nevada corporation and generally governed by the Nevada Private Corporations Code, Title 78 of the Nevada Revised Statutes (the "NRS").

Section 78.138 of the NRS provides that, unless the corporation's articles of incorporation provide otherwise, a director or officer will not be individually liable unless it is proven that (i) the director's or officer's acts or omissions constituted a breach of his or her fiduciary duties, and (ii) such breach involved intentional misconduct, fraud, or a knowing violation of the law. Our articles of incorporation provide the personal liability of our directors is eliminated to the fullest extent permitted under the NRS.

Section 78.7502 of the NRS permits a company to indemnify its directors and officers against expenses, judgments, fines, and amounts paid in settlement actually and reasonably incurred in connection with a threatened, pending, or completed action, suit, or proceeding, if the officer or director (i) is not liable pursuant to NRS 78.138, or (ii) acted in good faith and in a manner the officer or director reasonably believed to be in or not opposed to the best interests of the corporation and, if a criminal action or proceeding, had no reasonable cause to believe the conduct of the officer or director was unlawful. Section 78.7502 of the NRS requires a corporation to indemnify a director or officer that has been successful on the merits or otherwise in defense of any action or suit. Section 78.7502 of the NRS precludes indemnification by the corporation if the officer or director has been adjudged by a court of competent jurisdiction, after exhaustion of all appeals, to be liable to the corporation or for amounts paid in settlement to the corporation, unless and only to the extent that the court determines that in view of all the circumstances, the person is fairly and reasonably entitled to indemnity for such expenses and requires a corporation to indemnify its officers and directors if they have been successful on the merits or otherwise in defense of any claim, issue, or matter resulting from their service as a director or officer.

Section 78.751 of the NRS permits a Nevada company to indemnify its officers and directors against expenses incurred by them in defending a civil or criminal action, suit, or proceeding as they are incurred and in advance of final disposition thereof, upon determination by the stockholders, the disinterested board members, or by independent legal counsel. If so provided in the corporation's articles of incorporation, bylaws, or other agreement, Section 78.751 of the NRS requires a corporation to advance expenses as incurred upon receipt of an undertaking by or on behalf of the officer or director to repay the amount if it is ultimately determined by a court of competent jurisdiction that such officer or director is not entitled to be indemnified by the company. Section 78.751 of the NRS further permits the company to grant its directors and officers' additional rights of indemnification under its articles of incorporation, bylaws, or other agreement.

Section 78.752 of the NRS provides that a Nevada company may purchase and maintain insurance or make other financial arrangements on behalf of any person who is or was a director, officer, employee, or agent of the company, or is or was serving at the request of the company as a director, officer, employee, or agent of another company, partnership, joint venture, trust, or other enterprise, for any liability asserted against him and liability and expenses incurred by him in his capacity as a director, officer, employee, or agent, or arising out of his status as such, whether or not the company has the authority to indemnify him against such liability and expenses.

Our articles of incorporation provide for indemnification of our officers and directors to the fullest extent permissible under Nevada General Corporation Law, in accordance with the Company's Bylaws. Our Bylaws provide for indemnification of our officers and directors to the fullest extent not prohibited by the Nevada; provided however, that the Company may modify the extent of such indemnification by individual contracts with its directors and officers; and provided, further, that the Company shall not be required to indemnify any director or officer in connection with any proceeding (or part thereof) initiated by such person unless (i) such indemnification is expressly required to be made by law; (ii) the proceeding was authorized by the Board of Directors; (iii) such indemnification is provided by the Company, in its sole discretion, pursuant to the powers vested in the corporation under the Nevada General Corporation Law or; (iv) such indemnification is a result of the enforcement of a contractual right.

ITEM 15. RECENT SALES OF UNREGISTERED SECURITIES

Stockholders' Equity

Three Months Ended June 30, 2019

In April 2019, pursuant to Section 4(a)(2) of the Securities Act, the Company issued 800,000 shares of common stock for the conversion of the notes payable in the principal amount of $160,000.

Three Months Ended March 31, 2019

In January 2019, pursuant to Section 4(a)(2) of the Securities Act, the Company issued 60,000 shares of common stock with a fair value of $26,600 to service providers.

In February 2019, pursuant to Section 4(a)(2) of the Securities Act, the Company issued 268,615 shares of common stock for conversion of notes payable and accrued interest in the amount of $53,723.

Twelve Months Ended December 31, 2018

In January and March 2018, pursuant to Section 4(a)(2) of the Securities Act, the Company sold 260,000 shares of common stock to accredited investors in a private placement for cash of $47,000.

In January 2018, pursuant to Section 4(a)(2) of the Securities Act, the Company issued 1,200,000 shares of common stock with a fair value of $138,000 to management and board members.

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In May 2018, pursuant to Section 4(a)(2) of the Securities Act, the Company sold 150,000 shares of common stock to accredited investors who are family members of Robert J Bowdring, a Board Member in a private placement for cash of $30,000.

In May 2018, pursuant to Section 4(a)(2) of the Securities Act, the Company issued 3,020,000 shares of common stock with a fair value of $1,540,000 to a board member, Dr. Kevin Doody for services previously provided to the Company.

In October 2018, pursuant to Section 4(a)(2) of the Securities Act, the Company issued 4,895,076 shares of common stock with a fair value of $1,914,831 to employees and service providers.

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In December 2018, pursuant to Section 4(a)(2) of the Securities Act, the Company issued 887,306 shares of common stock with a fair value of $349,602 to employees and service providers.

Twelve Months Ended December 31, 2017

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In April 2017, pursuant to Section 4(2) of the Securities Act, the Company issued 51,750 shares of restricted common stock with a fair value of $17,201 to service providers.

In June 2017, pursuant to Section 4(2) of the Securities Act, the Company issued 99,412 shares of restricted common stock with a fair value of $30,898 to service providers.

In September 2017, pursuant to Section 4(2) of the Securities Act, the Company issued 133,960 shares of restricted common stock with a fair value of $28,576 to service providers.

In September 2017, pursuant to Section 4(2) of the Securities Act, the Company issued 262,500 shares of restricted common stock for cash proceeds of $44,625.

In November 2017, pursuant to Section 4(2) of the Securities Act, the Company issued 395,550 shares of restricted common stock with a fair value of $79,215 to service providers.

In November 2017, pursuant to Section 4(2) of the Securities Act, the Company issued 55,556 shares of restricted common stock for cash proceeds of $10,000.

2018 Convertible Notes Payable

In April and May 2018, the Company issued convertible notes (the "2018 Convertible Notes") payable to investors in the aggregate principal amount of $895,000. The 2018 Convertible Notes accrue interest at the rate of 9% per annum which is paid in stock. 2018 Convertible Notes with an aggregate principal amount of $550,000 are due on January 30, 2021, and 2018 Convertible Notes with an aggregate principal amount of $345,000 are due on March 31, 2021. The notes are convertible into shares of common stock at a price of $0.20 per share, provided, that if the Company completes a subsequent equity financing, the holders of the 2018 Convertible Notes can elect to convert the notes in shares of our common stock at a price equal to 75% of the price paid per share in such subsequent equity financing. During the fourth quarter of 2018, three note holders converted their notes with a value of $200,000 into 1,055,415 shares of common stock. During the first 6 months of 2019, the Company issued 268,615 shares of common stock for conversion of notes payable and accrued interest in the amount of $53,723 and 800,000 shares of common stock in connection with the conversion of a note payable in the principal amount of $160,000.

The Company calculated a beneficial conversion feature of the 2018 Convertible Notes based on ASU 17-11 in the form of a discount of $895,000; $366,126 of this amount was amortized to interest expense during the twelve months ended December 31, 2018, based on the three year term of the notes. In addition $53,564 of interest was expensed in the year ended December 31, 2018.

During the three months ended March 31, 2019 $93,237 of this amount was amortized to interest expense . In addition $14,870 of interest was expensed in the first quarter ended March 31, 2019.

ITEM 16. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) (1) Our un-audited and audited financial statements are included in the prospectus.

EXHIBIT NUMBER	DESCRIPTION
3.1	Articles of Incorporation of INVO Bioscience (1)
3.2	Certificate of Amendment to Articles of Incorporation of INVO Bioscience (1)
3.3	Certificate of Amendment to Articles of Incorporation of INVO Bioscience dated December 22, 2008 (2)
3.4	By-Laws of Registrant (3)
4.1	Form of Senior Secured Convertible Promissory Note – 2009 (4)
4.2	Form of Convertible Promissory Note Purchase Agreement – 2009 (4)
4.3	Form of Convertible Promissory Note – 2018 (5)
4.4	Form of Convertible Note Purchase Agreement – 2018 (5)
5.1	Opinion of Shulman Rogers *
10.1	Distribution Agreement between the Registrant and Ferring International Center S.A. (5) +
10.2	Supply Agreement between Registrant and Ferring International Center S.A. (5) +
10.3	Kathleen Karloff Loan Agreement (6)
10.4	Kathleen Karloff Revised Loan Agreement (7)
10.5	Promissory Note – August 2016 (5)
23.1	Consent of Liggett & Webb, P.A. *
23.2	Consent of Shulman Rogers (included in Exhibit 5.1) *

(1) Incorporated by reference to INVO Bioscience's predecessor EMY's Registration Statement on Form SB-2/A filed with the Securities and Exchange Commission on January 25, 2008.

(2) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 5, 2009.

(3) Incorporated by reference to the INVO Bioscience's predecessor EMY's Registration Statement SB-2 filed with the Securities and Exchange Commission on November 13, 2007.

(4) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 17, 2009.

(5) Incorporated by reference to the Registrant's Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 16, 2019.

(6) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the three months ended March 31, 2009 filed with the Securities and Exchange Commission on May 15, 2009.

(7) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the three months ended June 30, 2009 filed with the Securities and Exchange Commission on August 14, 2009.

* Filed herewith

+ Portions of this exhibit have been omitted in accordance with Item 601(b)(10) of Regulation S-K.

ITEM 17. UNDERTAKINGS

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) to include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in this registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) to include any material information with respect to the plan of distribution not previously disclosed in this registration statement or any material change to such information in this registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective 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-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

Insofar as indemnification for 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.

The undersigned registrant hereby further undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance under Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4), or 497(h) under the Securities Act of 1933 shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus 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.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City Beverly in the Commonwealth of Massachusetts, on July 29, 2019.

INVO BIOSCIENCE, INC.

By: /s/ Kathleen T. Karloff_____
Kathleen T. Karloff
Chief Executive Officer

We the undersigned officers and directors of INVO Bioscience, hereby severally constitute and appoint Kathleen T. Karloff and Robert Bowdring, our true and lawful attorney-in-fact and agent, with full power of substitution and re-substitution in her, for her, and in her name, place and stead, and in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Registration Statement (or any other Registration Statement for the same offering that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933), and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in- fact and agents full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as full to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent or his substitute may lawfully do or cause to be done by virtue hereof.

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

INVO BIOSCIENCE, INC.

By: /s/ Kathleen T. Karloff_____
Name: Kathleen T. Karloff
Title: Chief Executive Officer and Director
Date: July 29, 2019

By: /s/ Kevin Doody_____
Name: Kevin Doody, MD
Title: Medical Director and Director
Date: July 29, 2019

By: /s/ Robert J. Bowdring_____
Name: Robert J. Bowdring
Title: Secretary, Treasurer and Director
Date: July 29, 2019

By: /s/ Michael Campbell_____
Name: Michael Campbell
Title: Director
Date: July 29, 2019

By: /s/ Steven Shum_____
Name: Steven Shum
Title: Director
Date: July 29, 2019

Exhibit 5.1

July 29, 2019

Invo BioScience, Inc.
Attn: Robert Bowdring
407 Rear Mystic Avenue, Suite 34C
Medford, Massachusetts 02155

Re: Registration Statement on Form S-1

Dear Sir/Madam,

We have acted as special counsel to Invo Bioscience, Inc., a Nevada corporation (the "***Company***"), in connection with resale from time to time by the identified selling stockholders (the "***Selling Stockholders***") of up to 43,379,049 (the "***Shares***") of the Company's common stock, par value $0.0001 per share (the "***Common Stock***"), consisting of 4,888,048 shares of common stock issuable upon conversion of outstanding convertible promissory notes (the "***Notes***") with an aggregate principal amount of $520,000 (the "***Note Shares***") and 38,509,001 shares of common stock presently outstanding (the "***Outstanding Shares***"). The Shares are included in a registration statement on Form S–1 under the Securities Act of 1933, as amended (the "***Act***"), originally filed with the Securities and Exchange Commission (the "***Commission***") on December 20, 2018, as amended (the "***Registration Statement***"). This opinion is being furnished in connection with the requirements of Item 601(b)(5) of Regulation S-K under the Act, and no opinion is expressed herein as to any matter pertaining to the contents of the Registration Statement or related Prospectus, other than as expressly stated herein with respect to the issue of the Shares.

You have requested our opinions as to the matters set forth below in connection with the Registration Statement. For purposes of rendering our opinions, we have examined: (i) the Registration Statement, (ii) the amended and restated articles of incorporation of the Company, (iii) the Bylaws of the Company, (iv) certain resolutions of the Board of Directors of the Company and such other records of corporate actions of the Company relating to the Registration Statement and the authorization for issuance and sale of the Securities, and matters in connection therewith, (v) the following documents, each in the form filed with the Commission as exhibits to the Registration Statement: (a) the Notes, and (b) the agreements pursuant to which the Company issued such Notes, and (vi) the Company's stock ledger. We have also made such other investigation as we have deemed appropriate. We have examined and relied upon certificates of public officials and, as to certain matters of fact that are material to our opinions, we have also relied on a certificate of an officer of the Company.

In rendering our opinions, we have made the assumptions that are customary in opinion letters of this kind, including the assumptions of the genuineness of all signatures on original documents, the authenticity of all documents submitted to us as originals, the conformity to originals of all documents submitted to us as copies thereof, and the due execution and delivery of all documents where due execution and delivery are prerequisites to the effectiveness thereof.

Subject to the foregoing and the other matters set forth herein, it is our opinion that, as of the date hereof,

(1) The Outstanding Shares to be sold by the Selling Stockholders pursuant to the Registration Statement are validly issued, fully paid and nonassessable;
(2) The Note Shares have been duly authorized by all necessary corporate action of the Company, and upon issuance, delivery and payment therefor in accordance with the Notes, will be validly issued, fully paid and nonassessable.

This opinion is for your benefit in connection with the Registration Statement and may be relied upon by you and by persons entitled to rely upon it pursuant to the applicable provisions of the Act. We consent to your filing this opinion as an exhibit to the Registration Statement and to the reference to our firm in the Prospectus. In giving such consent, we do not thereby admit that we are in the category of persons whose consent is required under Section 7 of the Act or the rules and regulations of the Commission thereunder.

Very truly yours,

SHULMAN, ROGERS, GANDAL, PORDY & ECKER, P.A.

By: /s/ SHULMAN, ROGERS, GANDAL, PORDY & ECKER, P.A

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the use in this Form S-1 Registration Statement under The Securities Act of 1933 of our report dated April 16, 2019, which includes an explanatory paragraph regarding the substantial doubt about the Company's ability to continue as a going concern, included in the Annual Report for the year ended December 31, 2018 and 2017, relating to the financial statements of INVO Bioscience, Inc., which appear in such Registration Statement and related Prospectus for the registration of shares of its common stock.

We also consent to the references to us under the heading “Experts” in such Registration Statement.

/s/ Liggett & Webb, P.A.
LIGGETT & WEBB, P.A.

July 29, 2019
New York, New York