# **INVO Bioscience Reports 2019 Financial Results**

SARASOTA, Fla., March 30, 2020 — INVO Bioscience, Inc. (OTCQB: INVO), a medical device company focused on creating alternative treatments for patients diagnosed with infertility and developers of INVOcell®, the world's only in vivo Intravaginal Culture System, today announced financial results for the year ended December 31, 2019.



#### 2019 Financial Results:

- Revenue for the year totaled \$1,480,213 compared to \$494,375 in 2018, an increase of 199% in 2019. The growth was driven primarily by increased product sales in the U.S. as the Company's U.S. commercialization partner, Ferring International Center, S.A. ("Ferring"), began to ramp their marketing activities as well as from recognizing \$714,286 of the \$5,000,000 Ferring seven-year U.S. exclusive licensing & distribution fee.
- Gross margin for the year ended December 31, 2019 was approximately 91% compared to approximately 82% in 2018.
- Incurred a net loss of \$(2,167,544) during the year ended December 31, 2019 compared to a net loss of \$(3,076,091) during 2018, as a result of increased commercialization efforts.
- Company concluded the year ended December 31, 2019 with a cash position of approximately \$1.24 million.

### **Recent Operational Highlights**

- U.S. clinic locations which are trained to offer INVOcell have nearly tripled since our agreement with Ferring. Each clinic location will vary in terms of implementation time and growth. Ferring has established a website, www.invocell.com, which provides information for patients and health care professionals, in addition to providing a tool to search for clinic locations that offer INVOcell.
- Signed joint venture agreement with Medesole Healthcare and Trading Pvt Ltd to operate dedicated INVOcell fertility clinics in India. The joint venture has set an initial objective of opening three INVOcell clinics over the initial 12 months, with additional clinics planned in subsequent years.
- Received Institutional Review Board (IRB) approval to commence a planned clinical trial to evaluate the modified INVOcell system for effectiveness of achieving fertilization,

implantation, embryo development, clinical pregnancy, and live birth after 5-days of continuous vaginal incubation.

- Signed initial distribution agreements covering Nigeria, Turkey, Jordan, Uganda, Ethiopia, and Sudan in late 2019.
- Attained receipt of a CE Mark for the INVOcell culture and retention device in October 2019, a key requirement to commercially distribute through the European Union.
- Appointed Inger Britt Carlsson, PhD, as the Company's Vice President of Medical Affairs in February 2020. Dr. Carlsson will be developing and overseeing INVO Bioscience's educational symposiums, generating scientific abstracts/publications on the INVOcell technology, and building relationships with key opinion leaders around the world.
- Appointed Yve Lyppens as Director Business Development Asia Pacific in March 2020. Based in Hong Kong, Mr. Lyppens will be responsible for developing the Company's sales and distribution network throughout Asia.
- Changed our ticker symbol to "INVO" in March 2020 to align our public market trading symbol with our corporate name and our innovative fertility solution to improve the consistency of our branding along with our overall recognition within the investment community.

### **Management Discussion**

The Assisted Reproductive Technology (ART) Market continues to benefit from, in our opinion, a number of key industry tailwinds, which are not only contributing to a strong growth rate, but also increased investor interest.

Steve Shum, Chief Executive Officer of INVO Bioscience, commented, "We are pleased with the progress being made toward expanding the adoption of our technology, INVOcell, as a disruptive alternative in the infertility industry. Over the last year the number of U.S. clinic locations that are trained to offer INVOcell has nearly tripled, while we also executed on a number of key initiatives to expand our commercial efforts outside the U.S., including the receipt of our CE mark, signing additional distribution agreements in parts of Africa and Eurasia, and signing a joint venture in India to operate dedicated INVOcell clinics. And we continue to experience growing interest in many other parts of the world. In addition, we have made key additions to our team and expect to make a few additional strategic hires during 2020 to help further support our expanded commercialization, market education, and regulatory efforts."

Shum continued, "The growing awareness of INVOcell can be seen through the overall heightened social media activity and the increasing number of inbound inquires our team is experiencing. We have also witnessed certain early adopting clinics becoming increasingly more active with promoting INVOcell as the preferred infertility solution, over IVF, with its lower cost, more natural approach, and equivalent success rates. Equally important, INVOcell has allowed these practices to substantially increase their capacity and hence treat more patients as a result of improved efficiencies, particularly within the lab."

"We expect to see the 2018 Society For Assisted Reproductive Technology (SART) data published in the coming weeks ahead, at which point we will have a full two-years (2017 and 2018) of published retrospective data on INVOcell usage in the marketplace, which we believe will significantly enhance our marketing and commercialization efforts by further validating the success of the INVOcell technology. As previously highlighted, we also received approval to begin our planned clinical trial to evaluate the modified INVOcell system for effectiveness of achieving fertilization, implantation, embryo development, clinical pregnancy, and live birth after 5-days of continuous vaginal incubation, which will also further validate the technology and support the now growing volume of retrospective data reflecting real market usage of the technology."

"In sum, we believe we are laying a strong foundation for the business that will enable INVOcell to become a major treatment option in the large and growing fertility market. While we are a small percentage of the market today, interest is growing, and we believe the technology is profound and offers many unique advantages over current treatment options, and thus has the opportunity to garner a significant percentage of the market over time. While the COVID-19 virus has impacted elective procedures, such as fertility care, in the short run, including delays in our current trial recruitment activities, it is unlikely to have an impact on the long-term trends currently in place. Also, our team remains active and productive during this time and are even benefitting from quicker responses from new potential partners, which is likely a result of those potential partners taking advantage of slowdowns in their businesses with the current outbreak. As a result, we are encouraged with the level of our business development activities," concluded Shum.

# **Financial Results**

Revenue for year ended December 31, 2019 was \$1,480,213, compared to \$494,375 for the same twelve-month period ended December 31, 2018. The increase was the result of product sales to Ferring as they began to ramp their marketing activities as well as from recognizing \$714,286 of the \$5 million Ferring seven-year U.S. exclusive licensing & distribution fee.

Gross margin reported for the year ended December 31, 2019 was approximately 91% or \$1,340,543 compared to 82% or \$404,008 for the year ended December 31, 2018. The increase in gross margin relates to the amortization of the up-front license payment, partially offset by a lower average fixed selling price on product sales.

Selling, general and administrative expenses were \$3,128,635 in fiscal 2019 compared to \$3,038,068 for the year ended December 31, 2018. The \$90,567 increase in selling, general and administrative expenses in the year ended December 31, 2019 was primarily the result of an increase in wages, professional fees, legal fees, a legal settlement and other corporate expenses, partially offset by lower costs related to FDA clearance support services. We began

to fund additional research and development ("R&D") efforts in 2019 in preparation for our upcoming clinical trial, anticipated to occur in 2020, and additional patent filings. Excluding the investment in inventory to support the clinical trial and patents, R&D expenses for 2020 were immaterial. During 2018 the Company did not fund any R&D activities.

Interest expense and financing fees were \$379,019 for the year ended December 31, 2019 compared to \$442,031 for the same period in 2018. The primary reason for the higher interest expenses in both 2019 and 2018 was related to the amortization of the debt discount on our 2018 Convertible Notes Payable.

The net loss for the twelve months ended December 31, 2019 was \$(2,167,544) as compared to a net loss of \$(3,076,091) for the same twelve-month period in 2018. The primary reason for the decrease in net loss was the result of our increased revenues and gross profits generated in 2019.

# **About INVO Bioscience**

We are a medical device company focused on creating simplified, lower cost treatments for patients diagnosed with infertility. Our solution, the INVO Procedure, is a new technology. The INVO Procedure is a revolutionary *in vivo* method of vaginal incubation that offers patients a more natural and intimate experience. Our lead product, the INVOcell, is a patented medical device used in infertility treatment and is considered an Assisted Reproductive Technology (ART). The INVOcell is the first Intravaginal Culture (IVC) system in the world used for the natural *in vivo* incubation of eggs and sperm during fertilization and early embryo development, as an alternative to traditional In Vitro Fertilization (IVF) and Intrauterine Insemination (IUI). Our mission is to increase access to care and expand fertility treatment across the globe with a goal to lower the cost of care and increase availability of care. For more information, please visit **http://invobioscience.com/** 

### Safe Harbor Statement

This release includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The Company invokes the protections of the Private Securities Litigation Reform Act of 1995. All statements regarding our expected future financial position, results of operations, cash flows, financing plans, business strategies, products and services, competitive positions, growth opportunities, plans and objectives of management for future operations, as well as statements that include words such as "anticipate," "if," "believe," "plan," "estimate," "expect," "intend," "may," "could," "should," "will," and other similar expressions are forward-looking statements. All forward-looking statements involve risks, uncertainties and contingencies, many of which are beyond our control, which may cause actual results, performance, or achievements to differ materially from anticipated results, performance, or achievements. Factors that may cause actual results to differ materially from those in the forward-looking statements include those set forth in our filings at **www.sec.gov**. We are under no obligation to (and expressly disclaim any such obligation to) update or alter our forward-looking statements, whether as a result of new information, future events or otherwise.

#### -Financial Tables to Follow-

#### INVO Bioscience, Inc. CONSOLIDATED STATEMENTS OF OPERATIONS

CONSOLIDATED STATE	F	or the Year Ended ecember 31, 2019	I	For the Year Ended Pecember 31, 2018	
Revenue:					
Product Revenue	\$	765,927	\$	494,375	
License Revenue	Ψ	714,286	φ	+9+,575	
Total Revenue	\$	1,480,213	\$	494,375	
Cost of Goods Sold	Ъ	139,670	φ	90,367	
Gross Margin		1,340,543		404,008	
•		1,540,545		404,000	
Selling, general and administrative		2 1 2 0 6 2 5		2 020 060	
expenses		3,128,635		3,038,068	
Total operating expenses		3,128,635		3,038,068	
Loss from operations		(1,788,092)		(2,634,060)	
Interest expense		379,019		442,031	
Total other expenses		379,019		442,031	
Loss before income taxes		(2,167,111)		(3,076,091)	
Provision for income taxes	+	(433)		-	
Net Loss	\$	(2,167,544)	\$	(3,076,091)	
Basic net loss per weighted average		(		(	
shares of common stock	\$	(0.01)	\$	(0.02)	
Diluted net loss per weighted average					
shares of common stock	\$	(0.01)	\$	(0.02)	
Basic weighted average number of shares					
of common stock		155,356,091		147,333,051	
Diluted weighted average number of					
shares of common stock		155,356,091		147,333,051	
CONSOLIDATED E	DALAN	December 31, December 31,			
			2019	2018	
ASSETS Current assets					
Cash		\$	1,238,585	\$ 212,243	
Accounts receivable net			7,558	225,899	
Inventory, net Prepaid expenses and other current assets			101,387 195,910	43,513 249,454	
Total current assets			1,543,440	731,109	
Property and equipment, net			93,055	34,446	
Other Assets: Capitalized patents, net			7,234	11,792	
Lease right of use, net			101,883		
Trademarks Total other assets			49,867	- 11 700	
Total assets		\$	158,984 1,795,479	11,792 \$     777,347	
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LIABILITIES AND STOCKHOLDERS' DEFICIENCY				
Current liabilities	+	271 520	÷	571.000
Accounts payable and accrued liabilities, including related parties	\$	371,530	\$	571,828
Accrued compensation		393,017		2,515,256
Deferred revenue		714,286		18,895
Current portion of lease liability		21,365		-
Note payable		-		131,722
Note payable – related party		-		97,743
Convertible notes, net of discount of \$0 and \$497,961		-		157,039
Convertible notes, related party – net of discount of \$0 and \$ 30,913		-		9,087
Income taxes payable		912		-
Total current liabilities		1,501,110		3,501,570
Commitments and contingencies (Note 12)		-		-
Lease liability, net of current portion		81,494		-
Deferred revenue		3,571,429		-
Convertible notes, net of discount		325,784		-
Convertible notes, net of discount – related party		28,824		-
Deferred tax liability		433		-
Total liabilities		5,509,074		3,501,570
Stockholders' deficiency				
Preferred Stock, \$.0001 par value; 100,000,000 shares authorized.		-		-
No shares issued and outstanding as of December 31, 2019 and December				
31, 2018, respectively				
Common Stock, \$.0001 par value; 200,000,000 shares authorized; 156,316,112				
and 154,292,497 issued and outstanding as of December 31, 2019 and				
December 31, 2018, respectively		15,631		15,429
Additional paid-in capital		20,159,540		18,981,570
Accumulated deficit		(23,888,766)		(21,721,222)
Total stockholders' deficiency		(3,713,595)		(2,724,223)
Total liabilities and stockholders' deficiency	\$	1,795,479	\$	777,347
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