INVO Bioscience Reports Third Quarter 2020 Financial Results

Company to Provide Investor Update on November 19 at 4:30pm ET (Details Below)

SARASOTA, Fla., Nov. 16, 2020 /PRNewswire/ — INVO Bioscience, Inc. (Nasdaq: 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 quarter ended September 30, 2020.

Recent Highlights

- Revenues of $336,071 in the third quarter of 2020 increased 37% sequentially and 11% compared to the year ago quarter.
- Effective November 13, 2020, shares of the Company's common stock began trading on the Nasdaq Capital Market.
- Established a joint venture to operate dedicated INVOcell fertility clinics in Mexico.
- Submitted a 510k with the U.S. Food and Drug Administration (FDA) for 5-day label expansion utilizing the retrospective data made available earlier this year.
- Strengthened the board with the addition of independent directors Barbara Ryan, Matthew Szot and Jeffrey J. Segal, M.D.
- Ended the quarter, September 30, 2020, with a cash position of approximately $0.9 million. In November 2020, the Company announced the execution of an underwriting agreement with Roth Capital Partners for an underwritten public offering of 3,625,000 shares of its common stock at a public offering price of $3.20 per share for expected total gross proceeds of $11.6 million. The offering is expected to close on November 17, 2020.
- Net loss for the third quarter totaled $(1.77) million, which included $(837,236) of non-cash charges primarily related to the debt discount amortization and stock-based compensation. Adjusted EBITDA for the third quarter period was $(934,788).

Management Discussion

"Sales during the third quarter ended September 30, 2020 increased 37% sequentially over the quarter ended June 30, 2020, driven by higher sales in the United States as our partner Ferring placed additional orders toward the required annual minimum," commented Steve Shum, Chief Executive Officer of INVO Bioscience. "Although the market for fertility treatment services has been affected by COVID-19 this year, we have utilized this period to put in place what we believe are the necessary and important building blocks to create an organization well positioned to rapidly expand the adoption of the INVOcell solution, and we are starting to recognize the benefit of this work. In our opinion, the additional retrospective data made available this year, which represented the second year of available INVOcell usage data, provides a critically important element for our commercialization efforts."

"One of our most recent developments included the signing of our second joint venture agreement to open dedicated INVO clinics, this one in Mexico with Dr. Francisco Arredondo and Dr. Ramiro Ramirez. Dr. Arredondo was one of the early adopters of the INVOcell solution while practicing in the United States. We continue to engage in active discussions with additional partners in many of the major fertility markets for both distribution agreements and joint-venture concepts."

"We also took what we believe were critical and necessary actions to strengthen the Company operationally, financially and functionally which we believe positions us well to execute on our initiatives. These included the hiring of highly accomplished industry individuals to drive the commercialization efforts; the raising of capital required to fund our key commercial and development programs; the appointment of independent board members to meet corporate governance requirements; and the listing of the Company on the Nasdaq. With our strengthened balance sheet, we believe we have the tools, infrastructure and people now in place to drive long-term adoption of INVOcell, grow revenue, achieve profitability and drive shareholder value," concluded Mr. Shum.

Market Update

- United States: We continue to focus our U.S. efforts on supporting our partner, Ferring, and establishing certain INVO clinics in accordance with our agreement. Although the effort to develop INVO clinics has taken longer than we originally envisioned, we believe we are making excellent progress and expect to provide updates near-term.
- Mexico: In September 2020, INVO Bioscience created a joint venture with Dr. Francisco Arredondo, MD MPH, a respected and experienced board certified reproductive endocrinologist, and Dr. Ramiro Ramirez, MD, a physician and owner of several successful enterprises in Mexico, focused on developing the Mexico market for INVOcell. Dr. Arredondo was an early adopter of the INVOcell solution as he began offering IVC via the INVOcell to his patients at fertility clinics in San Antonio and Austin in 2016. In 2017, due to the initial success in expanding the accessibility of infertility treatment to patients utilizing INVOcell, he decided to open a center where he would exclusively offer the INVOcell solution in McAllen, Texas. The new jointly owned operation is targeting to open the initial center in the city of Monterrey, Mexico in early 2021.
- India: INVO Biosciences' JV partnership, signed in January 2020, is focused on opening dedicated INVO-only clinics in the India marketplace. While these efforts have and continue to be delayed due to the pandemic and the various lockdowns, the joint-

venture’s revised target for establishing the first clinic is now first quarter of 2021.
- Africa and Eurasia: The Company previously executed distribution agreements in certain markets in Africa and Eurasia toward the end of 2019. Following execution of those agreements, the Company began the product registration and approval process in order to begin importing into those markets. The Company has received the first of the product registration approvals for Turkey and Jordan and is now working with those distribution partners to begin training and commercialization activities. Work is continuing with the remaining countries to complete registrations.
- New Markets: INVO Bioscience is targeting a number of additional markets outside the U.S. (OUS) and has discussions underway in Canada, Columbia, Spain, Macedonia, Indonesia, Russia, Malaysia, and China among others. The Company is maintaining its goal of adding additional OUS markets through distribution or partnerships before year end.

Clinical/Regulatory Update

The Company continues to advance its 5-day label expansion efforts. The clinical trial, which previously received IRB approval to begin recruitment, and was placed on hold earlier this year due to the pandemic, should be ready to resume shortly. Separately, a 510(k) application utilizing real world data to support label expansion was submitted and is now pending with the FDA. The Company received a request for additional information from the FDA and is preparing its response to those questions, expected to be submitted in January 2021.

Financial Results

Revenue for the three months ended September 30, 2020, was $336,071 compared to $303,571 for the same three-month period in 2019, an increase of 11%, and compared to $246,072 in the second quarter of 2020 ended June 30, 2020, an increase of 37%.

The gross margin reported for the three months ended September 30, 2020 was 92% compared to 85% for the three months ended September 30, 2019.

Selling, general and administrative expenses for the three months ended September 30, 2020 were $1,463,887 compared to $891,008 for the three months ended September 30, 2019. The increase of $572,879 or 64%, in the third quarter of 2020 was primarily the result of an increase in personnel expenses, stock-based compensation and other corporate expenses.

We began to fund additional research and development (“R&D”) efforts in 2020 in order to support our 5-day label expansion efforts, and additional patent filings. R&D expenses were $112,552 for the three months ended September 30, 2020. During the same period in 2019 we did not fund any R&D activity.

During the three months ended September 30, 2020, we incurred $504,061 in interest expense, compared to $47,462 in the three months period ended September 30, 2019. The increase of $456,599 or approximately 962% was primarily due to the increase in the amortization of the debt discount, debt issuance cost and interest on the 2020 Convertible Notes.

We reported a net loss of $1,771,827 for the three months ended September 30, 2020, compared to a net loss of $710,334 for the three months ended September 30, 2019. The increase of $1,061,493 or approximately 149%, is primarily due to an increase in operating expense, interest expenses and financing fees. Total non-cash related expenses in the period totaled $837,236, primarily associated with the debt amortization and equity-based expensing.

The Company ended the quarter ended September 30, 2020 with a cash position of approximately $0.9 million. In November 2020, the Company announced of its execution of an underwriting agreement with Roth Capital Partners for an underwritten public offering of 3,625,000 shares of its common stock at a public offering price of $3.20 per share. Upon closing of the offering, the gross proceeds to INVO Bioscience from this offering are expected to be $11.6 million.

Conference Call Details

INVO Bioscience has scheduled a conference call for Thursday, November 19, 2020, at 4:30 pm ET (1:30 pm PT) to review these results and recent events. Interested parties can access the conference call by dialing (877) 270-2148 or (412) 902-6510 or can listen via a live Internet webcast at https://www.webcaster4.com/Webcast/Page/2162/38898, which is also available in the Investor Relations section of the Company's website at https://www.invobioscience.com/investors/.

If you would like to submit a question to be addressed on the call, please email INVO@lythampartners.com.

A teleconference replay of the call will be available for seven days at (877) 344-7529 or (412) 317-0088, confirmation #10150131. A webcast replay will be available in the Investor Relations section of the Company's website at https://www.invobioscience.com/investors/ for 30 days.

About INVO Bioscience

INVO Bioscience, Inc. (Nasdaq: INVO) is an innovative medical device company developing solutions for the global infertility industry. INVO's goal is to increase access to care and expand fertility treatment across the globe while seeking to lower the cost and increase the availability of care. INVO's lead commercial product, the INVOcell, is a patented Assisted

Reproductive Technology (ART) used in the treatment of infertility. The INVOcell device and procedure is unique as 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), the revolutionary in vivo method of vaginal incubation offers patients a more natural and intimate experience. INVO Bioscience is headquartered in Sarasota, FL. 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.

CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2020 (unaudited)	**December 31, 2019** (unaudited)
ASSETS		
Current assets		
Cash	$ 908,289	$ 1,238,585
Accounts receivable	3,699	7,558
Inventory	241,484	101,387
Prepaid expenses and other current assets	218,667	195,910
Total current assets	1,372,139	1,543,440
Property and equipment, net of depreciation of $49,730 and $42,147 respectively	106,000	93,055
Other assets:		
Capitalized patents, net of amortization of $71,843 and $70,488 respectively	5,879	7,234
Lease right of use	84,953	101,883
Trademarks	87,347	49,867
Investment in joint ventures	32,674	
Total other assets	210,853	158,984
Total assets	$ 1,688,992	$ 1,795,479
LIABILITIES AND STOCKHOLDERS’ DEFICIENCY		
Current liabilities		
Accounts payable and accrued liabilities, including related parties	$ 455,978	$ 371,530
Accrued compensation – related party	532,592	393,017
Deferred revenue, current portion	714,286	714,286
Current portion of lease liability	22,356	21,365
Notes payable	157,620	–
Income taxes payable	–	912
Total current liabilities	1,882,832	1,501,110

Lease liability, net of current portion	64,436	81,494
Deferred revenue, net of current portion	3,035,714	3,571,429
Convertible notes, net of discount of $3,008,258 and $174,310 respectively	607,521	325,784
Convertible notes – related party, net of discount of $0 and $17,151 respectively	–	28,824
Deferred tax liability	433	433
Total liabilities	5,590,936	5,509,074
Stockholders' deficiency		
Preferred Stock, $.0001 par value; 100,000,000 shares authorized; No shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	–	–
Common Stock, $.0001 par value; 200,000,000 shares authorized; 4,953,910 and 4,884,879 issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	495	489
Additional paid-in capital	24,525,427	20,174,682
Accumulated deficit	(28,427,866)	(23,888,766)
Total stockholders' deficiency	(3,901,944)	(3,713,595)
Total liabilities and stockholders' deficiency	$ 1,688,992	$ 1,795,479

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

	For the Three Months Ended September 30, 2020	**For the Three Months Ended September 30, 2019**	**For the Nine Months Ended September 30, 2020**	**For the Nine Months Ended September 30, 2019**
Revenue:				
Product revenue	$ 157,500	$ 125,000	$ 305,000	$ 615,927
License revenue	178,571	178,571	535,714	535,714
Total Revenue	336,071	303,571	840,714	1,151,641
Cost of Goods Sold	27,398	44,926	78,562	111,186
Gross Margin	308,673	258,645	762,152	1,040,455
Research and development	112,552	–	177,492	–
Selling, general and administrative expenses	1,463,887	891,008	4,311,872	2,087,725
Total operating expenses	1,576,439	891,008	4,489,364	2,087,725
Loss from operations	(1,267,766)	(632,363)	(3,727,212)	(1,047,270)
Interest expense	504,061	47,462	811,888	332,677
Total other expenses	504,061	47,462	811,888	332,677
Loss before income taxes	(1,771,827)	(679,825)	(4,539,100)	(1,379,947)
Provision for income taxes	–	(30,509)	–	(30,509)
Net Loss	$ (1,771,827)	$ (710,334)	$ (4,539,100)	$ (1,410,456)
Basic net loss per weighted average shares of common stock	$ (0.36)	$ (0.15)	$ (0.92)	$ (0.29)
Diluted net loss per weighted average shares of common stock	$ (0.36)	$ (0.15)	$ (0.92)	$ (0.29)
Basic weighted average number of shares of common stock	4,946,125	4,861,377	4,932,405	4,847,074
Diluted weighted average number of shares of common stock	4,946,125	4,861,377	4,932,405	4,847,074

Adjusted EBITDA

	Three Months Ended September 30 2020	Nine Months Ended September 30 2020
Net Loss	$ (1,771,827)	$ (4,539,100)
Additions:		
Interest Expense	88,963	133,845
Provision for Income taxes	–	–
Stock-based compensation	74,201	480,975
Stock Option expense	255,797	852,187
Amortization of Debt discount	415,098	678,043
Depreciation and amortization	2,980	8,938
Adjusted EBITDA*	**$ (934,788)**	**$ (2,385,112)**

**Adjusted to also include non-cash, stock-based expensing*

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