INVO Bioscience Reports Third Quarter 2021 Financial and Operating Results and Provides Business Update

Company to Host Conference Call Today at 4:30pm ET (Details Below)

SARASOTA, Fla., Nov. 15, 2021 /PRNewswire/ — INVO Bioscience, Inc. (Nasdaq: INVO) ("INVO" or the "Company"), a medical device company focused on creating alternative treatments for patients diagnosed with infertility and developers of INVOcell®, the world's only in vivo culture system, today announced financial and operating results for the third quarter ended September 30, 2021, and provided a business update.

Recent Operational Highlights

- Set to regain full U.S. commercialization rights for INVOcell® due to Ferring's termination for convenience of its Distribution Agreement with INVO effective January 31, 2022 (and the corresponding termination of the related Supply Agreement between Ferring and INVO), enabling the Company to sell directly into existing IVF clinics, to expand the number of INVO Centers free of any limitations, and to pursue a more aggressive market expansion strategy to increase access to care.
- Initial treatment cycles commenced at the Company's first U.S.-based INVO Center in Birmingham, Alabama following its opening in August 2021.
- Opened the second U.S.-based INVO Center in Atlanta, Georgia, in September 2021. The practice began seeing patients and performed its initial treatment cycles last week.
- Opened the first international INVO Center, and third overall in Monterrey, Mexico, on November 1, 2021. The Monterrey INVO Center has begun seeing patients, with the first cycles scheduled to occur later this year.
- Completed its acquisition of a Canadian-based entity, originally formed to offer INVOcell®, to advance its distribution in Canada.
- Signed a partnership agreement with Lyfe Medical, LLC to establish and operate an INVO Center in the San Francisco Bay area to offer the INVOcell®.
- Four poster abstracts discussing INVOcell® were presented at the 77th Scientific Congress & Expo of the American Society for Reproductive Medicine ("ASRM") held in Baltimore, Maryland in October 2021.
- Completed a $4.0 million registered direct offering of common stock priced at-the-market under Nasdaq rules with participation from INVO Bioscience's management team. The Company also entered into a stock purchase agreement for the sale of

approximately $2 million of its common stock at a fixed price, expected to close on or before November 30, 2021.
- Revenue was $218,874 for the quarter ended September 30, 2021, compared to $336,071 for the quarter ended September 30, 2020.
- Adjusted EBITDA for the third quarter of 2021 was $(1.6) million, which included $0.3 million loss attributable to our joint ventures, compared to $(0.9) million in the prior year's third quarter (see Adjusted EBITDA Table).

"We continue to execute against our core mission of improving access to advanced fertility services for the many patients around the world through the use of the INVOcell solution," commented Steve Shum, CEO of INVO Bioscience. "During the quarter, we achieved a significant milestone with the opening of our very first INVO Center, based in Birmingham, where we have commenced initial cycles. Further, we opened clinics in Atlanta, Georgia and Monterrey, Mexico to expand the INVO Center business model and we are working to open the San Francisco Bay Area clinic as soon as possible. We completed the acquisition of a Canadian-based entity that will be used to distribute the INVOcell in Canada and to develop INVO Centers in the region. With our INVO Center strategy now successfully underway, we are optimistic on the prospects for further expansion using this unique and innovative model. As part of a detailed review, we have initially identified more than 20 cities here in the U.S. that we believe have excellent characteristics in terms of demographics and level of current fertility care that would be ideal locations for an INVO Center."

"As an important development to our ability to expand the INVO Center model, we will regain full U.S. commercialization rights to INVOcell® from Ferring in early 2022, which removes certain limitations we had on expanding this business model in the U.S. Further, it allows us to resume direct sales to IVF clinics in our home territory and further expand our channel development plan. With our strong team of leaders highly experienced in commercializing advanced reproductive technologies, we are optimistic about our prospects as we pursue our multi-channel market expansion strategy."

"In addition to the opening of our INVO Center in Monterrey, Mexico, we continue to advance our international commercialization plans. Clinical validation of INVOcell® continues to grow with four poster abstracts presented at ASRM this year."

Shum concluded, "We are excited about the recent developments to advance commercialization of the INVOcell® solution. We look forward to leveraging the recent success of our INVO Centers, particularly in the U.S. With a great team, board of directors, and key advisors in place, we believe we have laid a strong foundation to achieve our goal of democratizing advanced fertility treatment with the INVOCell® solution, which should lead to strong revenue growth going forward."

Financial Results

Revenue for the three months ended September 30, 2021, was $0.2 million, compared to $0.3 million for the same three-month period in 2020. Of the $0.2 million in revenue for 2021, $37,513 was related to clinic revenue from the consolidated Alabama JV, the INVO Center was only open for part of the period and still in the early ramp up phase. The decrease in overall sales was related to a decrease in product sales to Ferring.

Gross margin reported for the three months ended September 30, 2021, was 91% compared to approximately 92% for the three months ended September 30, 2020.

Selling, general and administrative expenses for the three months ended September 30, 2021, were $2.4 million compared to $1.5 million for the three months ended September 30, 2020. The increase of $0.9 million was primarily the result of increased expenses related to the operations of the consolidated Alabama JV and increased personnel and public company expenses. We also incurred $0.5 million of non-cash, stock-based compensation expense in the period, compared to $0.3 million for the same period in the prior year.

We began to fund additional research and development ("R&D") efforts in 2021 as part of our 5-day label expansion efforts. R&D expenses were $0.06 million and $0.10 million for the three months ended September 30, 2021, and September 30, 2020, respectively.

Loss from equity investments for the three months ended September 30, 2021, was $0.1 million compared to $0 for the three months ended September 30, 2020. The increase in loss is due to the investment in the Georgia JV, which became operational late in the third quarter and is still in the early ramp-up phase.

Interest expense and financing fees were $0.09 million for the three months ended September 30, 2021, compared to approximately $0.5 million for the three months ended September 30, 2020.

Net loss attributable to INVO Bioscience for the three months ended September 30, 2021, was $(2.2) million compared to $(1.8) million for the three months ended September 30, 2020.

Adjusted EBITDA (see Adjusted EBITDA Table) for the three months ended September 30, 2021, was $(1.6) million, compared to adjusted EBITDA of $(0.9) million for the three months ended September 30, 2020.

As of September 30, 2021, the Company had approximately $4.7 million in cash. Subsequent to the end of the quarter, the Company completed a $4.0 million registered direct common stock offering priced at-the-market under Nasdaq rules.

Use of Non-GAAP Measure

Adjusted EBITDA is a non-GAAP measure. This measure is not intended to be a substitute for

those financial measures reported in accordance with GAAP. Adjusted EBITDA has been included because management believes that, when considered together with the GAAP figures, it provides meaningful information related to our operating performance and liquidity and can enhance an overall understanding of financial results and trends. Adjusted EBITDA may be calculated by us differently than other companies that disclose measures with the same or similar terms. See our attached financials for a reconciliation of this non-GAAP measure to the nearest GAAP measure.

Conference Call Details

INVO Bioscience has scheduled a conference call for Monday, November 15, 2021, 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 (833) 756-0861 or (412) 317-5751 or can listen via a live Internet webcast at https://www.webcaster4.com/Webcast/Page/2162/43563, which is also available in the Investor Relations section of the Company's website at https://www.invobioscience.com/investors/. A teleconference replay of the call will be available through November 22, 2021, at (877) 344-7529 or (412) 317-0088, confirmation #10161468. A webcast replay will be available in the Investor Relations section of the Company's website at https://www.invobioscience.com/investors/ for 90 days.

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 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 the availability of care. For more information, please visit **www.invobio.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.

INVO BIOSCIENCE, INC.
CONSOLIDATED BALANCE SHEETS
(UNAUDITED)

		September 30, 2021		December 31, 2020
ASSETS				
Current assets				
Cash	$	4,713,119	$	10,097,760
Accounts receivable		50,659		21,699
Inventory		290,390		265,372
Prepaid expenses and other current assets		275,818		157,700
Total current assets		5,329,986		10,542,531
Property and equipment, net		854,130		132,206
Capitalized patents, net		21,703		5,427
Lease right of use		1,391,228		79,319
Trademarks		110,445		89,536
Notes receivable from joint ventures		200,579		–
Other assets		–		240
Investment in joint ventures		237,476		98,084
Total assets	$	8,145,547	$	10,947,343
LIABILITIES AND STOCKHOLDERS’ EQUITY				
Current liabilities				
Accounts payable and accrued liabilities, including related parties	$	515,583	$	328,927
Accrued compensation – related party		461,911		527,326
Deferred revenue, current portion		714,286		714,286
Lease liability, current portion		107,513		22,707
Notes payable – Payroll Protection Program		–		157,620
Convertible notes, net		340,539		536,063
Income taxes payable		–		1,062
Total current liabilities		2,139,832		2,287,991
Lease liability, net of current portion		1,327,693		58,634
Deferred revenue, net of current portion		2,321,429		2,857,143
Deferred tax liability		469		469
Total liabilities		5,789,423		5,204,237
Stockholders’ equity				
Common Stock, $.0001 par value; 125,000,000 shares authorized; 10,464,035 and 9,639,268 issued and outstanding as of September 30, 2021 and December 31, 2020, respectively		1,046		964
Additional paid-in capital		41,343,118		37,978,224
Accumulated deficit		(38,749,497)		(32,236,082)
Noncontrolling interest		(238,543)		–
Total stockholders’ equity		2,356,124		5,743,106
Total liabilities and stockholders’ equity	$	8,145,547	$	10,947,343

INVO BIOSCIENCE, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Revenue:				
Product revenue	$ 2,790	$ 157,500	$ 538,642	$ 305,000
Clinic revenue	37,513		37,513	–
License revenue	178,571	178,571	535,714	535,714
Total revenue	$ 218,874	$ 336,071	$ 1,111,869	$ 840,714
Cost of goods sold:				
Production costs	17,987	24,966	90,464	71,268
Depreciation	2,431	2,432	7,294	7,294
Total cost of goods sold	20,418	27,398	97,758	78,562
Gross profit	198,456	308,673	1,014,111	762,152
Operating expenses				
Selling, general and administrative expenses	2,416,791	1,463,887	6,581,516	4,311,872
Research and development expenses	55,391	112,552	152,674	177,492
Total operating expenses	2,472,182	1,576,439	6,734,190	4,489,364
Loss from operations	(2,273,726)	(1,267,766)	(5,720,079)	(3,727,212)
Other income (expense):				
Loss from equity method joint venture	(113,492)	–	(113,492)	–
Other income	–	–	159,126	–
Interest income	(843)	–	3,595	–
Interest expense	(92,544)	(504,061)	(1,078,895)	(811,888)
Foreign currency exchange loss	(721)	–	(2,213)	–
Total other expenses	(207,600)	(504,061)	(1,031,879)	(811,888)
Net loss	(2,481,326)	(1,771,827)	(6,751,958)	(4,539,100)
Net loss attributable to noncontrolling interest	(238,543)	–	(238,543)	–
Net loss attributable to INVO Bioscience, Inc.	$ (2,242,783)	$ (1,771,827)	$ (6,513,415)	$ (4,539,100)
Net loss per common share:				
Basic	$ (0.24)	$ (0.36)	$ (0.66)	$ (0.92)
Diluted	$ (0.24)	$ (0.36)	$ (0.66)	$ (0.92)
Weighted average number of common shares outstanding:				
Basic	10,463,981	4,946,125	10,267,495	4,932,405
Diluted	10,463,981	4,946,125	10,267,495	4,932,405

Adjusted EBITDA

	Three Months Ended September 30		Nine Months Ended September 30	
	2021	2020	2021	2020
Net loss attributable to Invo Bioscience, Inc.	$ (2,242,783)	$ (1,771,827)	$ (6,513,415)	$ (4,539,100)
Other Income	$ –	$ –	(159,126)	–
Interest expense	$ 15,563	$ 88,963	60,341	133,845
Foreign currency exchange loss	$ 721	$ –	2,213	–
Stock-based compensation	$ 130,123	$ 74,203	557,331	480,975
Stock option expense	$ 391,194	$ 255,797	1,151,800	852,187
Amortization of debt discount	$ 77,824	$ 415,098	1,014,959	678,043
Depreciation and amortization	$ 17,721	$ 2,980	23,680	8,938
Adjusted EBITDA	**$ (1,609,637)**	**$ (934,786)**	**$ (3,862,217)**	**$ (2,385,112)**
Loss from equity method JV	$ 113,492		$ 113,492	$ –
Loss from consolidated JV (less depreciation)	$ 223,802		223,802	
Adjusted EBITDA for INVO corporate	**$ (1,272,342)**	**$ (934,786)** #	**$ (3,524,923)**	**$ (2,385,112)**

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