

## **INVO Bioscience Reports Second Quarter 2021 Financial and Operating Results and Provides Business Update**

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

SARASOTA, Fla., Aug. 16, 2021 /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 culture system, today announced financial and operating results for the second quarter ended June 30, 2021 and provides a business update.



### **Recent Operational Highlights**

- Officially opened the first U.S.-based INVO Center, located in Birmingham, Alabama in partnership with reproductive specialists Dr. Nicholas Cataldo, MD, MPH, Dr. Karen R. Hammond, DNP, CRNP, and Lisa Ray, MS, ELD. The new Birmingham practice, named “Innovative Fertility Specialists, an INVO Center” will provide fertility treatment utilizing the efficient, effective, and affordable INVOcell option. The practice has begun seeing patients and expects to perform initial treatment cycles in September 2021.
- Signed a joint venture agreement with Bloom Fertility to open an INVO Center in Atlanta, Georgia. Led by reproductive specialist Dr. Sue Ellen Carpenter, M.D., the center is scheduled to open in September 2021.
- Completed the site build-out and preparing to open the Company’s INVO Center JV in Monterrey, Mexico, Positib Fertility, with Drs. Francisco Arredondo and Ramiro Ramirez. Expected to open in the October timeframe.
- Signed a partnership agreement with Lyfe Medical, LLC to establish and operate a clinic in the San Francisco Bay area to offer the INVO procedure. Lyfe Medical will own the clinic while INVO will set-up and manage an embryology center to provide laboratory services to the clinic and its patients in exchange for a share of the clinic’s revenue.
- Expanded capabilities within the global OB/GYN vertical with the appointment of Barbara Levy, M.D., FACOG, FACS as the SVP, global clinical integration. Dr. Levy is considered one of the most influential reproductive health clinical executives in the world, recently serving as Vice President, Health Policy at the American College of Obstetricians and Gynecologists (ACOG) and chair of the American Medical Association/Specialty Society Relative Value Scale Update Committee.
- Appointed Andrea Goren as CFO, replacing the Company’s past utilization of an outside

CFO consulting firm, to lead the Company's finance function and to support the execution of the Company's strategic business plan, including the operational launch of the Company's INVO Center joint ventures.

## **Financial Highlights**

- Revenues were \$208,472 for the quarter ended June 30, 2021, compared to \$246,072 for the quarter ended June 30, 2020.
- Net loss for the second quarter of 2021 was approximately \$(1.8) million, which included approximately \$(0.7) million of non-cash charges primarily related to the debt discount amortization and equity-based compensation.
- Adjusted EBITDA for the second quarter of 2021 was \$(1.3) million, which included \$93,969 of JV start-up costs, compared to \$(0.8) million in the prior year's second quarter (see Adjusted EBITDA Table).
- As of June 30, 2021, the Company had a cash position of approximately \$6.6 million.

## **Management Discussion**

"Our team made excellent progress during the second quarter of 2021 toward our key objectives, headlined by last week's official opening of our first INVO Center practice in Birmingham, Alabama," commented Steve Shum, CEO of INVO Bioscience. "We feel INVO is now well positioned for success based on the following core foundational elements developed over the past 2 years:

1. Our Team - An experienced internal operating team with key positions filled, a strong and diverse board of directors, a scientific advisory board composed of well-known and respected fertility industry experts, and key outside KOL's/consultants.
2. Our Partners - A growing list of quality distributors around the world, experienced and motivated JV Partners, and a committed shareholder base.
3. Our Technology - We have gained valuable real market usage data (and hence further validation) along with a clear understanding of how our technology "fits" in the industry and the key challenges it helps solve.

We believe there is a substantial underserved patient population with infertility challenges and a real need to expand access to treatment. In our opinion, this is a multi-billion-dollar market expansion opportunity, and INVOcell is well positioned to address the unmet medical need."

"The new Birmingham practice, our very first INVO Center, is a major milestone and one of the most significant in the Company's history to date. The center is already off to an encouraging start as we have surpassed our internal expectations for patient appointments and expected treatment cycles planned for the first month. The vision to drive accelerated adoption of the INVOcell solution while also increasing much needed capacity and patient

access within the fertility industry is coming to reality with this first INVO Center, thanks to the expertise and commitment of our internal team and partners.”

Mike Campbell, COO further added, “With the blueprints now firmly in place for our INVO Center model, we are rapidly moving towards the opening of centers in Atlanta, Monterrey, Mexico and the San Francisco Bay area. We expect that Atlanta and Monterrey centers will both be opened before the end of the year, as site selections are complete, equipment has been ordered, staffing is ramping up, and marketing plans are in place. A San Francisco Bay area center should be opened shortly thereafter and our ongoing discussions with additional partners remain active. This is an exciting time for INVO as we have diversified our business model beyond device sales exclusively through our distributors, to a model where we will capture a share of the larger revenue generated by the entire INVO patient solution.”

Shum concluded, “Our goal to democratize fertility treatment by bringing care to the vast underserved patient population around the world experiencing infertility challenges is advancing. We believe a key to this effort will also involve leveraging the OB/GYN community. In July, we appointed Dr. Barbara Levy as our SVP, global clinical integration. Dr. Levy is considered one of the most influential fertility and reproductive health clinical executives in the world and brings a life-long passion to improving women’s health recognizing that a critical component to that is treatment for infertility. I am excited to have Dr. Levy help lead this OB/GYN strategy moving forward.”

## **Financial Results**

Revenues for the three months ended June 30, 2021 were approximately \$0.21 million, compared to approximately \$0.25 million for the same three-month period in 2020. The slight change was the result of a decrease in product sales to Ferring. Ferring’s minimum purchase requirements are based on a calendar year and hence contribute to quarterly fluctuations. Revenue pertaining to the Company’s INVO Centers will begin to be recognized in the current, third quarter.

Gross margin reported for the three months ended June 30, 2021 was approximately 93% compared to approximately 91% for the three months ended June 30, 2020.

Selling, general and administrative expenses for the three months ended June 30, 2021 were approximately \$2.0 million compared to approximately \$1.3 million for the three months ended June 30, 2020. The increase was primarily the result of increased personnel, board and business development consulting expenses, as well as startup costs related to our INVO Centers. We incurred approximately \$0.6 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 R&D efforts in 2020 as part of our 5-day label expansion efforts. R&D expenses were \$0.03 million for the three months ended June 30, 2021, compared to

\$0.03 million for the three months ended June 30, 2020.

Interest expense and financing fees were approximately \$0.09 million for the three months ended June 30, 2021, compared to approximately \$0.26 million for the three months ended June 30, 2020.

Net loss for the three months ended June 30, 2021 was approximately \$(1.8) million compared to approximately \$(1.3) million for the three months ended June 30, 2020. The increase in net loss was due to increased operating expenses.

Adjusted EBITDA (see Adjusted EBITDA Table) for the three months ended June 30, 2021 was \$(1.3) million, compared to adjusted EBITDA of \$(0.8) million for the three months ended June 30, 2020.

As of June 30, 2021, the Company had approximately \$6.6 million in cash compared to approximately \$8.4 million on March 31, 2021.

### **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, August 16, 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/2162/42110>, 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 August 23, 2021 at (877) 344-7529 or (412) 317-0088, confirmation #10158496. 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 <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](http://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)**

	<b>June 30, 2021</b>	<b>December 31, 2020</b>
ASSETS		
Current assets		
Cash	\$ 6,643,080	\$ 10,097,760
Accounts receivable	47,869	21,699
Inventory	250,784	265,372
Prepaid expenses and other current assets	289,843	157,700
Total current assets	7,231,576	10,542,531
Property and equipment, net	127,151	132,206
Capitalized patents, net	22,155	5,427
Lease right of use	1,419,925	79,319
Trademarks	107,287	89,536
Notes receivable	881,827	-
Other assets	-	240
Investment in joint ventures	141,267	98,084
Total assets	\$ 9,931,188	\$ 10,947,343
LIABILITIES AND STOCKHOLDERS' EQUITY		

Current liabilities			
Accounts payable and accrued liabilities, including related parties	\$	306,252	\$ 328,927
Accrued compensation		349,658	527,326
Deferred revenue, current portion		714,286	714,286
Lease liability, current portion		96,921	22,707
Note payable – Payroll Protection Program		–	157,620
Convertible notes, net		249,936	536,063
Income taxes payable		–	1,062
Total current liabilities		1,717,053	2,287,991
Lease liability, net of current portion		1,355,323	58,634
Deferred revenue, net of current portion		2,500,000	2,857,143
Deferred tax liability		469	469
Total liabilities		5,572,845	5,204,237
Stockholders' equity			
Common Stock, \$.0001 par value; 125,000,000 shares authorized; 10,459,035 and 9,639,268 issued and outstanding as of June 30, 2021 and December 31, 2020, respectively		1,046	964
Additional paid-in capital		40,864,011	37,978,224
Accumulated deficit		(36,506,714)	(32,236,082)
Total stockholders' equity		4,358,343	5,743,106
Total liabilities and stockholders' equity	\$	9,931,188	\$ 10,947,343

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

	For the Three Months Ended		For the Six Months Ended	
	June 30,		June 30,	
	2021	2020	2021	2020
Revenue:				
Product revenue	\$ 29,900	\$ 67,500	\$ 535,852	\$ 147,500
License revenue	178,572	178,572	357,143	357,143
Total revenue	\$ 208,472	\$ 246,072	\$ 892,995	\$ 504,643
Cost of goods sold:				
Production costs	12,163	18,739	72,477	46,301
Depreciation	2,432	2,431	4,863	4,863
Total cost of goods sold	14,595	21,170	77,340	51,164
Gross profit	193,877	224,902	815,655	453,479
Operating expenses				
Selling, general and administrative	2,049,422	1,252,939	4,164,725	2,847,985
Research and development	31,016	34,890	97,283	64,940
Total operating expenses	2,080,438	1,287,829	4,262,008	2,912,925
Loss from operations	(1,886,561)	(1,062,927)	(3,446,353)	(2,459,446)
Other income (expense):				
Other income	159,126	–	159,126	–
Interest income	2,425	–	4,438	–
Interest expense	(91,125)	(259,954)	(986,351)	(307,827)
Foreign currency exchange loss	(1,028)	–	(1,492)	–
Total other income (expense)	69,398	(259,954)	(824,279)	(307,827)
Loss before income taxes	(1,817,163)	(1,322,881)	(4,270,632)	(2,767,273)
Provision for income taxes	–	–	–	–
Net loss	\$ (1,817,163)	\$ (1,322,881)	\$ (4,270,632)	\$ (2,767,273)
Net loss per common share:				
Basic	\$ (0.17)	\$ (0.27)	\$ (0.42)	\$ (0.56)
Diluted	\$ (0.17)	\$ (0.27)	\$ (0.42)	\$ (0.56)
Weighted average number of common shares outstanding:				
Basic	10,444,150	4,932,942	10,167,624	4,925,469
Diluted	10,444,150	4,932,942	10,167,624	4,925,469

**Adjusted EBITDA**

	Three Months Ended		Six Months Ended	
	June 30		June 30	
	2021	2020	2021	2020
Net Loss	\$ (1,817,163)	\$ (1,322,881)	\$ (4,270,632)	\$ (2,767,273)
Other Income	(159,126)	–	(159,126)	–
Interest expense	9,707	(2,991)	44,778	44,882
Foreign currency exchange loss	1,492	–	1,492	–
Stock-based compensation	235,144	65,309	427,208	406,772
Stock option expense	384,083	214,915	760,606	596,390
Amortization of debt discount	76,980	223,027	937,135	262,945
Depreciation and amortization	(2,695)	(2,551)	5,959	5,958

**Adjusted EBITDA\***                      **\$ (1,271,579)**      **\$ (825,172)**      **\$ (2,252,580)**      **\$ (1,450,326)**  
*\*Adjusted to also include non-cash, stock-based expensing*

 View original content to download

multimedia:<https://www.prnewswire.com/news-releases/invo-bioscience-reports-second-quarter-2021-financial-and-operating-results-and-provides-business-update-301356114.html>

SOURCE INVO Bioscience, Inc.