

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

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

SARASOTA, Fla., May 17, 2021 — 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 first quarter of 2021 ended March 31, 2021 and provides a business update.



Recent Operational Highlights

- Signed an agreement to open the first U.S.-based INVOcell clinic, to be located in Birmingham, Alabama with an expected opening in the second half of 2021. The Birmingham facility will be a joint venture with a group of experienced reproductive specialists who have been strong advocates and successful adopters of the INVOcell solution.
- Signed a partnership agreement with Lyfe Medical, LLC focused on the expansion of the INVOcell solution in Northern California. Lyfe Medical will establish and operate a clinic in the San Francisco Bay Area to offer the INVO procedure to its patients while INVO Bioscience will establish and operate the embryology center to provide laboratory services in connection with the INVO procedure provided by Lyfe Medical to its patients.
- Regulatory approval received for INVOcell in Mexico in February 2021, allowing partner to target clinic opening in second half of 2021.
- Signed additional international agreements as well as began selling direct into Spain fertility clinics to complement the amended U.S. commercialization agreement with Ferring.
- Regular and active training sessions being held with distributors in various parts of the world and initial INVOcell cycles already being performed and initiated in Spain and Malaysia.
- Recent peer-reviewed publication further demonstrates excellent real-world success rates utilizing INVOcell and provides further clinical validation to support ongoing commercialization and partnering efforts – *Real-world experience with intravaginal culture using INVOCELL: an alternative model for infertility treatment – F&S Reports (fertstertreports.org)*

- Building substantial expertise in global marketing and brand building through the addition of current Senior Advisor at McKinsey & Co. former Global Chief Marketing Officer of Uber and Beam Suntory, Rebecca Messina joining the Board of Directors, and a 15-year women's health veteran, Meryle Lynn Chamberlain joining as the newly created position of Director of Marketing.

Financial Highlights

- Revenue increased approximately 165% to \$684,523 for the quarter ended March 31, 2021 compared to \$258,571 for the quarter ended March 31, 2020.
- Net loss for the first quarter of 2021 was approximately \$(2.5) million, which included approximately \$(1.4) million of non-cash charges primarily related to the debt discount amortization and stock-based compensation.
- Adjusted EBITDA for the first quarter of 2021 was \$(981,002), which included approximately \$224,000 of JV start-up costs, compared to \$(625,154) in the prior year's first quarter (see Adjusted EBITDA Table).
- As of March 31, 2021, the Company had a cash position of approximately \$8.4 million, with additional \$504,000 in account receivables received subsequent to quarter end.

Management Discussion

"This was an exciting start to the year 2021 for INVO Bioscience as we advanced our INVO Clinic strategy with the signing of our first U.S.-based INVOcell exclusive facility in Birmingham, Alabama, the signing of a partnership agreement to establish and operate a center in Northern California, and the completion of our product registration in Mexico. We expect these initial centers to become operational in the second half of the year," commented Steve Shum, Chief Executive Officer of INVO Bioscience. "Throughout this year, we have expanded our real-world experience data and positive results with INVOcell, enhanced our online training tools, materials, and capabilities and have experienced a substantial increase in active training sessions for our international partners and distributors. We believe the combination of strong commercialization partnerships and company-owned clinics, both in the U.S. and around the world, is key to expanding INVOcell's adoption within the fertility industry."

"In addition to the progress made executing new commercialization agreements, we have strengthened our marketing capabilities to support the INVOcell-only centers and our growing number of distribution partners. Meryle Lynn Chamberlain, a tenured women's health and fertility solution marketing professional, joined us as Director of Marketing in March 2021, while Rebecca Messina, current Senior Advisor at McKinsey & Co. and former Global Chief Marketing Officer at both Uber and Beam Suntory joined our board of directors in April 2021. As we look to increase access to care and expand fertility treatment across the globe, our market positioning and overall strategies are more important than ever. The addition of

Meryle Lynn and Rebecca will enhance our ability to successfully accomplish these goals.”

“As we look to the remainder of 2021, we have set a number of key objectives, including the opening of our first company-owned clinics in Mexico and the United States. Additionally, we will seek to build our international revenues this year through our growing list of international distribution partners as they finish training, and we complete local product registration requirements. Of note, we are extremely pleased to see the initial INVO procedures performed recently in Spain and Malaysia, which reflects the groundwork done by our team in these specific markets, which we believe will help in further expanding the overall awareness of the potential outside of the U.S. Finally, we are continuing to advance our 5-day label expansion efforts with the FDA in the U.S. market with a goal of completing this effort in 2021. It remains our belief that there is strong global demand for fertility services and INVOcell is well-positioned through our growing, global footprint to play a key role in helping to turn the dream of creating a family for millions of people around the world into a reality through our accessible, efficient, and affordable fertility treatment.”

Financial Results

Revenue for the three months ended March 31, 2021 was \$684,523, compared to \$258,571 for the same three-month period in 2020, an increase of approximately 165%. The increase was the result of sales to Ferring related to satisfying the minimum purchase requirements for 2020.

Gross margin reported for the three months ended March 31, 2021 was approximately 91% compared to approximately 88% for the three months ended March 31, 2020.

Selling, general and administrative expenses for the three months ended March 31, 2021 were approximately \$2.1 million compared to approximately \$1.6 million for the three months ended March 31, 2020. The increase of approximately \$0.5 million or 33% was primarily the result of approximately \$0.2 million in startup costs related to clinic joint ventures as well as approximately \$0.2 million in increased personnel and consulting expenses. We incurred approximately \$0.6 million of stock-based compensation expense in the period.

We began to fund additional research and development efforts in 2020 as part of our 5-day label expansion efforts, and also submitted additional trademark and patent filings. R&D expenses were \$66,267 for the three months ended March 31, 2021 compared to \$30,050 for the three months ended March 31, 2020.

Interest expense and financing fees were approximately \$0.9 million for the three months ended March 31, 2021, compared to approximately \$0.05 million for the three months ended March 31, 2020. The increase was primarily non-cash and due to an increase in amortization of debt discount, debt issuance costs and interest on the 2020 Convertible Notes.

Net loss for the three months ended March 31, 2021 was approximately \$(2.5) million compared to approximately \$(1.4) million for the three months ended March 31, 2020. The increase in net loss was due to increased operating expenses and interest expense. Approximately \$0.8 million of this increase was related to non-cash debt amortization expense along with approximately \$0.2 million in startup costs related to joint ventures.

Adjusted EBITDA (see Adjusted EBITDA Table) for the three months ended March 31, 2021 was \$(981,002), compared to adjusted EBITDA of \$(625,154) for the three months ended March 31, 2020.

As of March 31, 2021, the Company had approximately \$8.4 million in cash compared to approximately \$0.4 million on March 31, 2020.

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, May 17, 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/2162/40939>, 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 May 24, 2021 at (877) 344-7529 or (412) 317-0088, confirmation #10155249. 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. 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)

	March 31, 2021	December 31, 2020
ASSETS		
Current assets		
Cash	\$ 8,423,236	\$ 10,097,760
Accounts receivable	527,651	21,699
Inventory	268,349	265,372
Prepaid expenses and other current assets	363,969	157,700
Total current assets	9,583,205	10,542,531
Property and equipment, net	129,679	132,206
Capitalized patents, net	22,606	5,427
Lease right of use	73,644	79,319
Trademarks	100,885	89,536
Notes receivable	280,160	-
Other assets	-	240
Investment in joint ventures	-	98,084
Total other assets	477,295	272,606
Total assets	\$ 10,190,179	\$ 10,947,343
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities, including related parties	\$ 512,044	\$ 328,927

Accrued compensation - related party	267,390	527,326
Deferred revenue, current portion	714,286	714,286
Lease liability, current portion	23,061	22,707
Notes payable - Payroll Protection Program	157,620	157,620
Convertible notes, net	185,458	536,063
Income taxes payable	-	1,062
Total current liabilities	1,859,859	2,287,991
Lease liability, net of current portion	52,789	58,634
Deferred revenue, net of current portion	2,678,571	2,857,143
Deferred tax liability	469	469
Total liabilities	4,591,688	5,204,237
Stockholders' equity		
Common Stock, \$.0001 par value; 125,000,000 shares authorized; 10,424,229 and 9,639,268 issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	1,042	964
Additional paid-in capital	40,287,000	37,978,224
Accumulated deficit	(34,689,551)	(32,236,082)
Total stockholders' equity	5,598,491	5,743,106
Total liabilities and stockholders' equity	\$ 10,190,179	\$ 10,947,343


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

	For the Three Months Ended	
	March 31,	
	2021	2020
Revenue:		
Product revenue	\$ 505,952	\$ 80,000
License revenue	178,571	178,571
Total revenue	684,523	258,571
Cost of goods sold:		
Production costs	60,314	27,563
Depreciation	2,431	2,431
Total cost of goods sold	62,745	29,994
Gross profit	621,778	228,577
Selling, general and administrative expenses	2,115,303	1,595,046
Research and development	66,267	30,050
Total operating expenses	2,181,570	1,625,096
Loss from operations	(1,559,792)	(1,396,519)
Other income (expense):		
Interest income	2,013	-
Interest expense	(895,226)	(47,873)
Foreign currency exchange loss	(464)	-
Total other expenses	(893,677)	(47,873)
Loss before income taxes	(2,453,469)	(1,444,392)
Provision for income taxes	-	-
Net loss	\$ (2,453,469)	\$ (1,444,392)
Net loss per common share:		
Basic	\$ (0.25)	\$ (0.29)
Diluted	\$ (0.25)	\$ (0.29)
Weighted average number of common shares outstanding:		
Basic	9,888,025	4,917,997
Diluted	9,888,025	4,917,997

Adjusted EBITDA

	For the Three Months Ended	
	March 31,	
	2021	2020
Net loss	\$ (2,453,469)	\$ (1,444,392)
Add:		
Interest expense	35,071	47,873
Stock-based compensation	192,064	341,463

Stock option expense	376,523	381,475
Amortization of debt discount	860,155	39,918
Depreciation and amortization	8,654	8,509
Adjusted EBITDA	\$ (981,002)	\$ (625,154)

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multimedia:<http://www.prnewswire.com/news-releases/invo-bioscience-reports-first-quarter-2021-financial-and-operating-results-and-provides-business-update-301292744.html>

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