

INVO Bioscience Reports 2020 Financial Results

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

SARASOTA, Fla., March 30, 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 year ended December 31, 2020.



Recent Operational Highlights

- In March 2021, the Company 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 adopters of the INVOcell solution, having performed more than 700 cycles with INVOcell while in practice.
- In addition to the Birmingham clinic, the Company signed joint venture agreements to open dedicated INVOcell centers in Mexico and India during 2020.
- Regulatory approval for INVOcell in Mexico in February 2021 allows partner to target clinic opening in second half of 2021.
- In addition to the U.S. commercialization agreement with Ferring, the Company signed additional international agreements as well as began selling direct into Spain in early 2021 at three separate fertility clinics.
- During 2020, additional real-world evidence accrued, which continues to reflect the quality outcomes achieved in real world usage of INVOcell, memorialized in a published peer-reviewed manuscript by Ferring.
- Formed a Scientific Advisory Board (SAB) with the appointment of several prominent members of the fertility industry, including Tony Anderson, DHSc, ELD, Amber Cooper, MD, MSCI, FACOG, Karen R. Hammond, DNP, CRNP, and Francisco “Paco” Arredondo, MD, MPH, FACOG.
- Strengthened the board of directors with the addition of independent directors Barbara Ryan, Matthew Szot and Jeffrey J. Segal, M.D., J.D.
- Listed the Company's common stock on the Nasdaq Capital Market.

Financial Highlights

- Revenue for the year ended December 31, 2020 was \$1,037,286, compared to

\$1,480,213 for the ended December 31, 2019. Subsequent to the end of the year, Ferring placed a \$501,000 order for the remaining 2020 minimum contractual product purchase requirements, which will be recognized as revenue by INVO Bioscience in the first quarter of 2021.

- Net loss for 2020 was \$(8.3) million, which included \$(4.4) million of non-cash charges primarily related to the debt discount amortization and stock-based compensation. Adjusted EBITDA for 2020 was \$(3.7) million compared to \$(1.5) million in the prior year (see Adjusted EBITDA Table).
- As of December 31, 2020, the Company had a cash position of approximately \$10.1 million.

Management Discussion

“In the face of a difficult year for many industries, including the fertility business, I am extremely proud of the accomplishments of the entire INVO Bioscience team,” commented Steve Shum, Chief Executive Officer of INVO Bioscience. “During the year, we put in place a number of building blocks for the future, which are already beginning to pay dividends. Recently we announced our plan to open our first U.S.-based INVOcell clinic in partnership with some of the most highly accomplished INVOcell practitioners in the world. Our partners are not only extremely well-versed in the INVOcell technology, but also have a proven track record of successful implementation of the platform within an established clinical setting. A few months prior, we announced that we plan to open dedicated INVOcell clinics in Mexico with Dr. Francisco Arredondo and Dr. Ramiro Ramirez, who were also early adopters of the INVOcell solution and have established a successful track record of successful implementation of INVOcell in a clinical setting. We believe the combination of strong distribution partners such as Ferring in the U.S. and other locations around the world, coupled with dedicated INVOcell clinics partnerships which INVO Bioscience has an equity interest in, position the Company well for the future.”

“Another key development during the year was the availability of additional positive real-world usage data highlighting the success of INVOcell, including a published peer-reviewed manuscript (report). We expect to see further data from this year’s SART information in the near future. In our opinion, this expanded retrospective, real world validated data is extremely valuable to our commercial efforts and builds confidence with practitioners. We believe that this expanding portfolio of usage data will play an important role in expanding and accelerating market adoption.”

“In addition to expanded commercialization agreements and positive real-world usage data, we accelerated a number of other activities necessary to drive long-term adoption of INVOcell. In particular, we strengthened the Company with leaders on our board of directors and industry experts on the medical advisory board. With a strong team in place, and a balance sheet strengthened by our public offering and uplisting to Nasdaq, we remain

optimistic about the near and long-term future,” Mr. Shum concluded.

Clinical/Regulatory Update

The Company continues to advance its 5-day label expansion efforts and filed a 510K utilizing the expanded retrospective (real market usage) data. The Company is working to collect additional real-world information to support the submission and we plan to continue to provide updates as they become available.

Financial Results

Revenue for 2020 was \$1,037,286, compared to \$1,480,213 in 2019. The decrease was the result of a decline in product sales to Ferring. However, pursuant to an amendment we entered into subsequent to the year end, Ferring placed a \$501,000 purchase order in March 2021, which the Company agreed would satisfy Ferring’s minimum purchase requirements for 2020. Although the purchase order relates to the 2020 requirements, the company will record the revenue in the first quarter of 2021.

Gross margins were 91% in 2020, compared to 91% in 2019.

Selling, general and administrative expenses for 2020 were \$6,065,066, compared to \$3,128,635 in 2019. The increase was primarily the result of an increase in personnel, stock-based compensation, marketing and other corporate expenses. Approximately \$1,756,991 of this increase over 2019 was related to non-cash equity-based compensation.

The Company began to fund additional research and development (“R&D”) efforts in 2020 as part of its 5-day label expansion efforts, and also submitted additional trademark and patent filings. Excluding the investment in inventory in anticipation of clinical trials and patents, R&D expenses were \$398,426 for 2020. During 2019 we did not fund any R&D.

Interest expense and financing fees were \$2,836,504 for 2020, compared to \$387,646 in 2019. The increase was primarily due to an increase in non-cash amortization of discount, debt issuance costs and interest on the 2020 Convertible Notes and was primarily a non-cash related expense.

Net loss in 2020 was \$8,347,316 compared to \$2,167,544 in 2019. The increase in net loss was due to increased operating expenses, interest expense and non-cash expenses. Approximately \$2,626,168 of this increase was related to non-cash debt amortization expense along with \$1,756,991 of non-cash equity compensation.

Adjusted EBITDA (see Adjusted EBITDA Table) for 2020 was \$(3.74) million, compared to adjusted EBITDA of \$(1.54) million in 2019.

As of December 31, 2020, the Company had \$10,097,760 in cash compared to \$1,238,585 on

December 31, 2019.

Use of Non-GAAP Measure

Adjusted EBITDA is a non-GAAP measure. However, 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 term. 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 Tuesday, March 30, 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 (877) 270-2148 or (412) 902-6510 or can listen via a live Internet webcast at <https://www.webcaster4.com/Webcast/Page/2162/40436>, 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 April 6, 2021 at (877) 344-7529 or (412) 317-0088, confirmation #10153332. 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

	December 31, 2020	December 31, 2019
ASSETS		
Current Assets		
Cash	\$ 10,097,760	\$ 1,238,585
Accounts receivable, net	21,699	7,558
Inventory, net	265,372	101,387
Prepaid expenses and other current assets	157,700	195,910
Total Current Assets	10,542,531	1,543,440
Property and equipment, net	132,206	93,055
Other assets:		
Capitalized patents, net	5,427	7,234
Lease right of use	79,319	101,883
Trademarks	89,536	49,867
Other assets	240	-
Investments in joint ventures	98,084	-
Total other assets	272,606	158,984
Total assets	\$ 10,947,343	\$ 1,795,479
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIENCY)		
Current liabilities		
Accounts payable and accrued liabilities, including related parties	\$ 328,927	\$ 371,530
Accrued compensation	527,326	393,017
Deferred revenue	714,286	714,286
Current portion of lease liability	22,707	21,365
Notes payable - Payroll Protection Program	157,620	-
Convertible notes	536,063	-
Income taxes payable	1,062	912
Total current liabilities	2,287,991	1,501,110

Leasehold liability, net of current portion	58,634	81,494
Deferred revenue, net of current portion	2,857,143	3,571,429
Convertible notes	-	325,784
Convertible notes - related party, net	-	28,824
Deferred tax liability	469	433
Total liabilities	5,204,237	5,509,074
Stockholders' equity (deficiency)		
Preferred stock, \$.0001 par value; 100,000,000 shares authorized; No shares issued and outstanding as of December 31, 2020 and December 31, 2019, respectively	-	-
Common stock, \$.0001 par value; 125,000,000 shares authorized; 9,639,268 and 4,884,879 shares issued and outstanding as of December 31, 2020 and December 31, 2019, respectively	964	489
Additional paid-in capital	37,978,224	20,174,682
Accumulated deficit	(32,236,082)	(23,888,766)
Total stockholders' equity (deficiency)	5,743,106	(3,713,595)
Total liabilities and stockholders' equity (deficiency)	\$ 10,947,343	\$ 1,795,479

INVO BIOSCIENCE, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

For the Year Ended
December 31,
2020 **2019**

Revenue:		
Product revenue	\$ 323,000	\$ 765,927
License revenue	714,286	714,286
Total Revenue	\$ 1,037,286	\$ 1,480,213
Cost of Goods Sold:		
Production costs	79,035	133,664
Depreciation	9,725	6,006
Total Cost of Goods Sold	88,760	139,670
Gross profit	948,526	1,340,543
Operating expenses:		
Research and development expenses	398,426	-
Selling, general, and administrative expenses	6,065,066	3,128,635
Total operating expenses	6,463,492	3,128,635
Loss from operations	(5,514,966)	(1,788,092)
Other income (expense):		
Interest income	4,190	8,627
Interest expense	(2,836,504)	(387,646)
Total other income (expense)	(2,832,314)	(379,019)
Loss before income taxes	(8,347,280)	(2,167,111)
Provision for income taxes	(36)	(433)
Net loss	\$ (8,347,316)	\$ (2,167,544)
Net loss per common share:		
Basic	\$ (1.52)	\$ (0.45)
Diluted	\$ (1.52)	\$ (0.45)
Weighted average number of shares outstanding:		
Basic	5,489,738	4,854,878

Diluted 5,489,738 4,854,878

Adjusted EBITDA

	Twelve Months Ended December 31 2020	Twelve Months Ended December 31 2019
Net Loss	\$ (8,347,316)	\$ (2,167,544)
Add:		
Interest Expense	210,336	50,233
Provision for Income taxes	36	433
Stock-based compensation	616,002	157,500
Stock Option expense	1,140,989	69,787
Amortization of Debt discount	2,626,168	337,413
Depreciation and amortization	11,917	10,766
Adjusted EBITDA*	\$ (3,741,868)	\$ (1,541,412)

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

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