



NEWS RELEASE

Inotiv, Inc. Provides Business Update and Select Preliminary Fiscal Year 2022 Financial Results

2022-12-12

Delays Release of Full Financial Results for the Fourth Quarter and Fiscal Year Ended September 30, 2022

WEST LAFAYETTE, Ind., Dec. 12, 2022 (GLOBE NEWSWIRE) -- Inotiv, Inc. (NASDAQ: NOTV) (the "Company", "We", "Our" or "Inotiv"), a leading contract research organization specializing in nonclinical and analytical drug discovery and development services and research models and related products and services, announced today that it will delay the release and conference call related to its financial results for the fourth quarter and fiscal year ended September 30, 2022 ("FY 2022") that was originally scheduled for after market close today.

As previously disclosed, on November 16, 2022, the Company became aware that the U.S. Attorney's Office for the Southern District of Florida ("USAO-SDFL") had criminally charged employees of the Company's principal supplier (the "Supplier") of non-human primates ("NHPs"), along with two Cambodian officials, with conspiring to illegally import NHPs into the U.S. from December 2017 through January 2022 and in connection with seven specific imports between July 2018 and December 2021. Also as previously disclosed, two of the Company's subsidiaries, Orient BioResource Center and Envigo Global Services, Inc., companies acquired by the Company on January 27, 2022, and November 5, 2021, respectively, had received grand jury subpoenas from USAO-SDFL requiring the production of documents and information related to their importation of NHPs into the U.S. The Company has been fully cooperating, and will continue to cooperate, with USAO-SDFL.

As a result of these events, the Company requires additional time to complete the financial statement closing process for FY 2022. The Company intends to file a Form 12b-25 with the U.S. Securities and Exchange Commission providing the Company a 15-day extension to file its FY 2022 Annual Report on Form 10-K.

The Company is providing the following preliminary financial data for FY 2022:

- Total revenue for FY 2022 is expected to increase to approximately \$547.7 million from total revenue of \$89.6 million in FY 2021.
- Discovery and Safety Assessment (“DSA”) business book to bill ratio is expected to be 1.33x.
- DSA backlog is expected to increase to approximately \$147.2 million at September 30, 2022, up from \$81.4 million at September 30, 2021.

These expectations are preliminary and are subject to the completion of year-end accounting and financial reporting and audit procedures.

Since learning of the issues related to the Supplier, the Company has been focused on attempting to obtain additional information, assessing the impact on its NHP sale activities, communicating with its customers and lenders, and exploring all potential avenues to address this situation. While the situation is extremely fluid and continues to involve significant uncertainty, the Company would like to address what it expects are questions from its stakeholders.

How significant is the Cambodian supply of NHPs to U.S. Drug Discovery and Development?

According to the U.S. Centers for Disease Control and Prevention, in the twelve months ended September 30, 2022, approximately 60% of the NHPs imported into the U.S. were from Cambodia. We believe that, depending on the duration of restrictions on these imports, drug discovery and development in the U.S. could be materially impacted. NHPs are critical for scientific research, and are required by international regulatory guidance to develop and evaluate the safety and effectiveness of a range of life-saving drugs and treatments prior to their assessment in human clinical trials. Historically, the U.S. biomedical industry has relied on imported NHPs to meet its domestic demand for research and development of new medicines. The Company believes that other contract research organizations, the pharmaceutical industry, and departments of the U.S. government recognize the significance of this interruption in the supply chain for NHPs.

What is the Company’s position on use of NHPs in research?

The Company strongly condemns any and all unauthorized trading and importation of any endangered species. With respect to legal trading and importation, we believe there is a pressing need to reduce the numbers of animals used in drug discovery and research, and replace them with non-animal alternatives where possible. The Company also recognizes that it will take time to achieve safe methods to do so, and there will still be the need for NHPs in the foreseeable future.



Therefore, it is of critical importance to address NHP supply in the U.S. The Company believes there should be a strong focus on reaching stability in the domestic supply of NHPs to help further U.S. leadership in the development of drugs and therapies. The recent indictment has highlighted and accelerated the need for more robust importation controls in the immediate future to promote excellence and provide transparency. The Company believes that a near-term public-private partnership is essential for secure access to NHPs in the U.S., and the Company, through its commitment to animal welfare and sustainable governance, can be part of that solution. A public-private partnership is essential as well to develop a longer-term strategy for breeding in the U.S.

What is the status of the Cambodian NHPs currently in the Company's possession in the U.S.?

The Company has not been directed to refrain from selling the Cambodian NHPs in its possession in the U.S. However, due to the allegations contained in the indictment involving the Supplier and the Cambodian Government officials, the Company believes that it is prudent, at the present time, to refrain from selling or delivering any of its Cambodian NHPs held in the U.S. until the Company's staff and external experts can evaluate what additionally can be done to satisfy itself that the NHPs in inventory from Cambodia can be reasonably determined to be purpose-bred. Historically, the Company has relied on the CITES documentation and related processes and procedures, including release of each import by U.S. Fish and Wildlife Service.

What portion of the Company's sales have been from NHPs imported from Cambodia?

Of the Company's expected preliminary total revenue of \$547.7 million in FY 2022, approximately \$140 million was from NHPs that it had imported from Cambodia.

Is the Company currently importing any NHPs?

We have been informed that Cambodia has currently ceased any exports of NHPs, and therefore we are not currently importing any NHPs from Cambodia. We do not know when or if they intend to resume allowing shipments or when and if the U.S. Fish and Wildlife Service will allow shipments. We are importing NHPs from other countries, however, such imports are limited due to insufficient quantities to meet U.S. demand. Without imports from China (which are currently banned by China) and/or Cambodia, NHP supply to us, and to U.S. customers generally, will be increasingly limited.

What is the impact on the Company's NHP customers?

The Company is proactively discussing these matters with its NHP customers. At this time, none of those customers have notified the Company of a contract breach.

NHPs are used in the Company's Research Models and Services ("RMS") business; what about its DSA business?

On an annualized basis, the Company uses approximately 5% of its total imported NHPs for its own internal needs in the DSA segment. The Company currently expects that it will have NHPs from other origins in sufficient quantities to meet the needs of its DSA segment business in fiscal 2023.

Does this impact the Company's European NHP sales and its NHP service sales?

At this time, the Company does not expect that these matters will impact its European NHP sales, as it has not been selling Cambodian NHPs in Europe. In addition, the Company does not anticipate these matters will negatively impact its NHP service sales.

Why have these issues delayed the Company's reporting of financial results for FY 2022?

Under applicable accounting and financial reporting rules, certain events that occur after the end of a fiscal quarter can impact reporting of matters as of that fiscal quarter end. The Company determined that it requires additional time for further evaluation of the relevant current conditions and events, considered in the aggregate, as well as management's plans that are intended to mitigate those conditions and events. Furthermore, assessments of whether assets, tangible and intangible, such as goodwill and inventory, are impaired are dependent on several considerations, which are based in part on information and estimates as of a fiscal quarter end. Therefore, the Company is in the process of reviewing and assessing these subsequent events, their recent impact on the Company's stock price and their impact on the carrying value of its assets.

How are these issues impacting the Company's first fiscal quarter results?

The Company has not delivered any Cambodian NHPs held by it in the U.S. since November 16, 2022, when it became aware of this issue. If the Company is not able to resume such deliveries before the end of the quarter, its sales, earnings and liquidity in the first fiscal quarter ended December 31, 2022, will be negatively impacted.

Has the Company been discussing this matter with the appropriate U.S. regulators?

The Company is cooperating with the relevant regulators in this matter, and is attempting to obtain additional clarity on the application of the Supplier's issues to the NHPs that the Company holds in the U.S., as well as the impacts on the broader industry, research markets, and government agencies which use these research models in the U.S.

How is the Company planning for potential outcomes?

Due to the ongoing uncertainties and the fluidity of the situation, management has been assessing and planning around three potential scenarios, none of which has an estimated timeframe, and none of which is certain. Those alternative scenarios contemplate that at some undetermined point in the future:

- the Company will be able to sell the Cambodian NHPs currently held by it in the U.S., and will be able to import NHPs again from Cambodia; or
- the Company will be able to sell the Cambodian NHPs currently held by it in the U.S., but will not be able to import NHPs from Cambodia in the foreseeable future; or
- the Company will not be able to sell the Cambodian NHPs currently held by it in the U.S., and will not be able to import NHPs from Cambodia in the future.

How is this impacting the Company's credit facilities?

The Company has been in communication with its lenders related to these matters. The Company is not currently in default of any financial covenants; however, the Company has notified its lenders that it may need to request a waiver or amendment of the financial covenants under the Company's credit agreement based on the outcomes of its efforts to resolve the issues.

What is the Company doing in other areas?

While our focus on addressing the NHP matters is unwavering, we are not letting up on other aspects of our business. We continue to move forward with our recently completed expansions and addition of new service offerings in our DSA business. We are also proceeding with our previously-announced RMS site optimization plans. In addition, we are reviewing potential areas for reduction of expenses.

We are grateful to our employees and leadership for their strong efforts under these difficult circumstances.

About Inotiv

Inotiv, Inc. is a leading contract research organization dedicated to providing nonclinical and analytical drug discovery and development services and research models and related products and services. The Company's products and services focus on bringing new drugs and medical devices through the discovery and preclinical phases of development, all while increasing efficiency, improving data, and reducing the cost of taking new drugs to market. Inotiv is committed to supporting discovery and development objectives as well as helping researchers realize the full potential of their critical R&D projects, all while working together to build a healthier and safer world. Further information about Inotiv can be found here: <https://www.inotivco.com/>.

Cautionary Note Regarding Forward-Looking Statements

This press release contains statements that are forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Those statements include statements about the Company's efforts and ability to address NHP issues; the impact of these issues on the Company's business, operations, results of operations, financial position and cash flows; its FY 2022 preliminary expected total revenue amounts and expected book-to-bill ratio and backlog information; the potential need to obtain a waiver or amendment of its financial covenants and its lenders' reactions to these matters; the reaction of customers to these matters; portions of its business that are not affected by these issues; and the impact of these matters on its fourth quarter FY 2022 and its first quarter FY 2023 results. Such statements are based upon the current beliefs, expectations, and assumptions of management and are subject to significant risks, uncertainties, and changes in circumstances that could cause actual outcomes and results to differ materially from the forward-looking statements. Such risks and uncertainties include, but are not limited to, risks and uncertainties related to events related to the NHP issues, whether the Cambodian NHPs the Company holds in the U.S. will ever be able to be shipped, when and whether NHPs will be able to be exported from Cambodia and lack of supply of NHPs from other sources, the impact of these events on the valuation of the Company's assets, the Company's ability to comply with its covenants and obligations under its credit agreement, the Company's ability to obtain waivers or amendments related to its covenants under the credit agreement, the sufficiency of the Company's liquidity and cash flows to meet its obligations, the ability of the Company to complete its FY 2022 financial statement closing and audit process and file its Annual Report on Form 10-K by the extended due date, the identification of additional material weaknesses in the Company's internal control over financial reporting, changes in the market and demand for the Company's products and services, the development, marketing and sales of products and services, changes in technology, industry and regulatory standards, the timing of acquisitions and the successful closing, integration and business and financial impact thereof, governmental regulations, inspections and investigations, the impact of site closures and consolidations, expansion and related efforts, and various other market and operating risks, including those detailed in the Company's filings with the U.S. Securities and Exchange Commission. You are cautioned not to rely on these forward-looking statements, since there can be no assurance that these forward-looking statements will prove to be accurate. Forward-looking statements speak only as of the date they are made, and we expressly disclaim any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, except as required by law.

The FY 2022 expected total revenue amounts and expected book-to-bill ratio and backlog information in this press release are preliminary, have not been audited and are subject to change in connection with the completion of our financial statements for the three months ended September 30, 2022. In addition, our independent registered public accounting firm does not express an opinion or any other form of assurance with respect thereto. The preliminary figures may differ materially from the actual results that will be reflected in the Company's financial

statements when they are completed and publicly disclosed. Accordingly, you should not place undue reliance on this information. Additional information and disclosures would be required for a more complete understanding of our financial position and results of operations as of, and for the period ended on, September 30, 2022.

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Source: Inotiv, Inc.