

June 7, 2023



# Navidea Biopharmaceuticals, Inc. Reports First Quarter 2023 Financial Results and Provides Business Update

*Following recently reported financial results for its first quarter ending March 31, 2023, the Company provides additional insight on performance and objectives in line with its Fix, Fund, Propel approach to advancing its innovative technology to market.*

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE American: NAVB) ("Navidea" or the "Company"), a company focused on the development of precision immunodiagnostic agents and immunotherapeutics, today announces, in line with the Company's [Fix, Fund, Propel](#) approach, details related to recently reported financial results for its first quarter ended March 31, 2023 and provides a business update.

## **Fix, Fund, Propel - First Quarter 2023 and Additional Business Highlights**

Supported by G2G Ventures, executive consultants to Navidea, the Company's stated Fix, Fund, Propel framework to implement change initiatives which drive effective processes, improve liquidity, and create growth made headway in the first quarter of 2023, and continue to do so into the second quarter.

- (Fix) In March, the Company entered into a [Consulting Services Agreement](#) with G2G Ventures, the executive director of which is Joshua Wilson, a director of the Company. Under the agreement, G2G will provide executive-level support services to the Company.
- (Fix) In the first quarter of 2023, Selling, general and administrative expenses were down 36% compared to the same period in 2022.
- (Fix) Dr. Michael Rosol stepped down as Chief Medical Officer in April, while continuing in a consultative role, and [Michael Blue, M.D., FACEP was promoted to Chief Medical Officer](#) to lead the continued development of the Company's initiatives in innovative diagnostics and therapeutics, and advance the Company's NAV3-32 and NAV3-33 clinical trials to completion.
- (Fix) [Jill Bieker Stefanelli, Ph.D. joined the Company's Board of Directors](#) adding deep experience developing and advancing precision medicine products in line with Navidea's objective to advance innovative technology to market. Separately, Alexander L. Cappello stepped down from the Board.
- (Fix) The Company promoted Simon Alder Blackburn, CCRA to Associate Director of Clinical Research and Operations, reporting to CMO, and with responsibility for supervising providers and recommending and implementing product development, corporate strategy, and marketing initiatives.
- (Fix) Enrollment into the Company's NAV3-33 Phase 3 trial in rheumatoid arthritis ("RA") titled "Evaluation of Tc 99m Tilmanocept Imaging for the Early Prediction of

Anti-TNF $\alpha$  Therapy Response in Patients with Moderate to Severe Active Rheumatoid Arthritis” continues its momentum.

- (Fund) In April, John K. Scott Jr agreed to loan the Company up to \$300,000 under the terms of a secured bridge note to support the Company’s operations.
- (Fund) In April, the Company entered into a Common Stock Purchase Agreement with Keystone Capital Partners, LLC whereby Keystone committed to purchase up to \$2,750,000 of shares of the Company’s common stock.
- (Fund) In May, the Company [announced the sale](#) of \$1.1 million in preferred shares to two investors, providing additional capital to advance the Company’s NAV3-32 and NAV3-33 clinical trials toward completion.
- (Fund/Propel) In April, the Company entered into an [Asset Purchase Agreement](#) with Meilleur Technologies, Inc., pursuant to which Meilleur agreed to acquire certain assets and assume certain liabilities of the Company relating to its business of developing and commercializing PET biomarkers for Alzheimer’s Disease. As part of the purchase, Meilleur paid a cash payment of \$250,000 to the Company at closing and agreed to make a cash payment of \$500,000 to the Company within 60 days after the closing date. In addition, certain future payments may be made to the Company, including contingent payments and milestone payments based on potential licensing events, regulatory submissions, regulatory approvals, and net sales of any approved product derived from the purchased business.

*“I remain confident Navidea’s transformative technology holds the potential to improve lives around the world,” said Dr. Michael Blue, Chief Medical Officer of Navidea. “Our team of experts, with G2G’s support, are making great progress on the changes required to place our innovative solutions in the hands of those who need them most.”*

*“From the onset, we’ve been thrilled for the opportunity to work with this unique organization,” said Dr. Jason Myers, Owner and Founder of G2G Ventures. “Our expertise lies in translating technologies into differentiated products, building infrastructure and process, and in creating strategies that drive growth. Our approach, in concert with the determination of the team at Navidea, is working. It’s a process to move the Company’s underappreciated technology and assets to the forefront - and more work remains to reach our goals.”*

## **First Quarter 2023 Financial Results**

- During the three-month periods ended March 31, 2023 and 2022, the Company did not recognize license revenue, revenue from contracts with customers, any related impairment losses, revenue from performance obligations associated with long-term contracts that were satisfied (or partially satisfied) in previous periods, nor grant revenue.
- Research and Development Expenses. R&D expenses increased \$98,000, or 8%, to approximately \$1.3 million during the first quarter of 2023 from \$1.2 million during the same period in 2022. The increase was primarily due to net increases in drug project expenses related to (i) increased Manocept diagnostic development costs of \$503,000 including increased manufacturing-related activities and increased clinical trial costs; and (ii) increased Tc99m tilmanocept development costs of \$8,000, primarily European regulatory consulting expenses; offset by (iii) decreased Manocept therapeutic development costs of \$82,000 including decreased preclinical and clinical development

costs and decreased manufacturing-related activities. The net increase in R&D expenses also included increased regulatory consulting expenses of \$30,000 offset by decreased employee compensation including fringe benefits and incentive-based awards of \$334,000, decreased recruiting fees of \$17,000 and decreased general office expenses of \$10,000.

- **Selling, General and Administrative Expenses.** Selling, general and administrative expenses decreased \$655,000, or 36%, to approximately \$1.2 million during the first quarter of 2023 from \$1.8 million during the same period in 2022. The decrease was primarily due to decreased legal and professional services of \$501,000, decreased employee compensation including fringe benefits and incentive-based awards of \$62,000, decreased losses on the abandonment of certain intellectual property of \$47,000 and decreased director fees of \$45,000 related to decreased board compensation rates.
- **Other Income (Expense).** Other income, net, was \$946,000 during the first quarter of 2023 compared to other expense, net, of \$8,000 during the same period in 2022. During the first quarter of 2023, we recognized a gain on amendment of contracts of \$1.2 million resulting from an amendment to our license agreement with UCSD for the exclusive world-wide rights to all diagnostic and therapeutic uses of tilmanocept (other than Tc99m tilmanocept used in lymphatic mapping). The amendment released the Company from any and all obligations related to certain diligence requirements as defined in the license agreement. During the first quarters of 2023 and 2022, we recognized interest expense of \$263,000 and \$4,000, respectively. The increase was primarily due to increases in interest expenses related to the Bridge Note of \$142,000 and the CRG judgement of \$115,000.
- Navidea's net loss attributable to common stockholders for the three-month period ended March 31, 2023 was approximately \$1.5 million, or \$0.05 per share, compared to approximately \$3.0 million, or \$0.10 per share, for the same period in 2022.

## **About Navidea**

Navidea Biopharmaceuticals, Inc. (NYSE American: NAVB) is a biopharmaceutical company focused on the development of precision immunodiagnostic agents and immunotherapeutics. Navidea is developing multiple precision-targeted products based on its Manocept platform to enhance patient care by identifying the sites and pathways of disease and enable better diagnostic accuracy, clinical decision-making, and targeted treatment. Navidea's Manocept platform is predicated on the ability to specifically target the CD206 mannose receptor expressed on activated macrophages. The Manocept platform serves as the molecular backbone of Tc99m tilmanocept, the first product developed and commercialized by Navidea based on the platform. Navidea's strategy is to deliver superior growth and shareholder return by bringing to market novel products and advancing the Company's pipeline through global partnering and commercialization efforts. For more information, visit [www.navidea.com](http://www.navidea.com).

## **About G2G Ventures**

G2G Ventures is a Colorado-based private equity firm focused on empowering organizations to reach their full potential through investment and consulting services. Specializing in creating long-term partnerships with trusted investors and established businesses, G2G Ventures draws on strong internal balance sheet liquidity, augmented by trusted investor

capital, to craft bespoke capital solutions which include private equity investment, venture capital participation, and mezzanine debt options. Beyond financial investment, G2G Ventures provides accretive consulting services to help clarify strategic goals and key performance indicators (KPIs), evolve financial processes, and enhance operational effectiveness. To learn more about how G2G Ventures is a growth partner for enduring business, [connect](#) with our team.

## **Forward-Looking Statements**

This press release contains 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. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends affecting the financial condition of our business. Forward-looking statements include our expectations regarding pending litigation and other matters. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, among other things: our history of operating losses and uncertainty of future profitability; the final outcome of any pending litigation; our ability to successfully complete research and further development of our drug candidates; the timing, cost and uncertainty of obtaining regulatory approvals of our drug candidates; our ability to successfully commercialize our drug candidates; dependence on royalties and grant revenue; our ability to implement our growth strategy; anticipated trends in our business; our limited product line and distribution channels; advances in technologies and development of new competitive products; our ability to comply with the NYSE American continued listing standards; our ability to maintain effective internal control over financial reporting; and other risk factors detailed in our most recent Annual Report on Form 10-K and other SEC filings. You are urged to carefully review and consider the disclosures found in our SEC filings, which are available at <http://www.sec.gov> or at <http://ir.navidea.com>.

Investors are urged to consider statements that include the words “will,” “may,” “could,” “should,” “plan,” “continue,” “designed,” “goal,” “forecast,” “future,” “believe,” “intend,” “expect,” “anticipate,” “estimate,” “project,” and similar expressions, as well as the negatives of those words or other comparable words, to be uncertain forward-looking statements.

You are cautioned not to place undue reliance on any forward-looking statements, any of which could turn out to be incorrect. We undertake no obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this report. In light of these risks and uncertainties, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially from those anticipated or implied in the forward-looking statements.

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Source: Navidea Biopharmaceuticals, Inc.