
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): December 13, 2018

Alliqua BioMedical, Inc.

(Exact name of registrant as specified in its charter)

DELAWARE
(State or other jurisdiction
of incorporation)

001-36278
(Commission
File Number)

58-2349413
(I.R.S. Employer
Identification No.)

2150 Cabot Blvd., West
Suite B
Langhorne, PA
(Address of principal executive offices)

19047
(Zip Code)

Registrant's telephone number, including area code (215) 702-8550

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events.

On December 13, 2018, Adynxx, Inc. (“Adynxx”) issued a press release announcing the receipt of a Notice of Award from the National Institute on Drug Abuse, part of the National Institutes of Health, for an award to support the clinical development of the company’s lead product candidate, brivolidige injection for postoperative pain. The full text of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Additional Information about the Merger and Where to Find It

In connection with the Agreement and Plan of Merger and Reorganization (the “Merger Agreement”), pursuant to which, among other things, subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Embark Merger Sub Inc. will merge with and into Adynxx, with Adynxx becoming a wholly-owned subsidiary of the Company and the surviving corporation of the merger (the “Merger”), the Company intends to file relevant materials with the SEC, including a definitive proxy statement for its stockholders containing the information with respect to the Merger and the Merger Agreement specified in Schedule 14A promulgated under the Securities Exchange Act of 1934, as amended, and describing the proposed Merger. The preliminary proxy statement and other relevant materials (when they become available), and any other documents filed by the Company with the SEC, may be obtained free of charge at the SEC’s website at www.sec.gov. In addition, investors and security holders may obtain free copies of the documents filed with the SEC by the Company by directing a written request to: Alliqua BioMedical, Inc., 2150 Cabot Boulevard West, Suite B, Langhorne, Pennsylvania 19047. Investors and security holders are urged to read the proxy statement and the other relevant materials when they become available before making any voting or investment decision with respect to the Merger.

Participants in Solicitation

The Company and its directors and executive officers and Adynxx and its directors and executive officers may be deemed to be participants in the solicitation of proxies from the stockholders of the Company in connection with the proposed transaction. Information regarding the special interests of these directors and executive officers in the Merger will be included in the proxy statement referred to above. Additional information regarding the directors and executive officers of the Company is also included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2017 and the proxy statement for the Company’s 2018 Annual Meeting of Stockholders. These documents are available free of charge at the SEC’s website at www.sec.gov and from the Company at the address described above.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995 and other federal securities laws. The use of words such as “may,” “might,” “will,” “expect,” “plan,” “anticipate,” “believe,” “intend,” “future,” or “continue” and other similar expressions are intended to identify forward-looking statements. For example, all statements Adynxx makes regarding the initiation, timing, progress, and reporting of results of its preclinical programs, clinical trials, and research and development programs; its ability to advance its product candidates into and successfully initiate, enroll, and complete clinical trials; the timing or likelihood of its regulatory filings and approvals; and success and market acceptance of its product candidates, are forward-looking. All forward-looking statements are based on estimates and assumptions by Adynxx’s management that, although Adynxx believes to be reasonable, are inherently uncertain. All forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those that Adynxx expected. Such risks and uncertainties include, among others, the initiation and conduct of preclinical studies and clinical trials; the availability of data from clinical trials; the expectations for regulatory submissions and approvals; the continued development of its product candidates; Adynxx’s scientific approach and general development progress; and the availability or commercial potential of Adynxx’s product candidates. These statements are also subject to a number of material risks and uncertainties that are described in Alliqua BioMedical, Inc.’s preliminary proxy statement, filed with the Securities and Exchange Commission on November 26, 2018. Any forward-looking statement speaks only as of the date on which it was made. Adynxx undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

| Exhibit No. | Description |
|------------------------|---|
| <u>99.1</u> | <u>Press release of Adynxx, Inc., dated December 13, 2018</u> |

* * *

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: December 13, 2018

ALLIQUA BIOMEDICAL, INC.

By: /s/ Joseph Warusz
Joseph Warusz
Chief Financial Officer

ADYNXX ANNOUNCES NOTICE OF AWARD FOR \$5.7M IN FEDERAL GRANT FUNDING

Award intended to fund Phase 2 study of brivoligide in patients undergoing mastectomy

SAN FRANCISCO, Calif., December 13, 2018 -- Adynxx, Inc., a clinical-stage biotechnology company focused on developing transformative therapies for pain and inflammatory diseases, today announced receipt of Notice of Award from the National Institute on Drug Abuse (NIDA), part of the National Institutes of Health (NIH), for an award to support the clinical development of the company's lead product candidate, brivoligide injection (brivoligide) for postoperative pain.

"This award provides Adynxx with the opportunity to augment and accelerate the development of brivoligide," said Dr. Julien Mamet, PhD, founder and Chief Scientific Officer of Adynxx and Co-Primary Investigator on the funding award. "In addition to dramatically reducing postoperative pain, our previous studies have suggested that brivoligide can substantially reduce opioid consumption for up to three months after surgery. We appreciate having the support of NIDA on this unique approach to reducing postoperative opioid utilization and the subsequent risk for opioid use disorders."

The funding opportunity (RFA-DA-19-002), titled "Development of Medications to Prevent and Treat Opioid Use Disorders and Overdose," is a UG3/UH3 Phase Innovation Awards Cooperative Agreement involving two phases. The UG3 phase is to support a project with specific milestones to be accomplished by the end of the 2-year period. The UH3 phase is to provide funding for 3 years to a project that successfully completed the milestones set in the UG3 phase. Application budgets are limited to \$3 million direct costs per year and UG3 projects that have met their milestones will be considered by NIDA and prioritized for transition to the UH3 phase, with the total funding currently expected to be available under both the UG3 and UH3 phases to be a maximum of \$15 million in direct costs.

The grant award received by Adynxx will provide Adynxx with \$5.7 million over the two-year UG3 phase to complete a Phase 2 study of brivoligide in patients undergoing mastectomy with immediate tissue expander or implant placement that score high on the Pain Catastrophizing Scale (PCS). Following completion of milestones related to the Phase 2 mastectomy study, Adynxx can receive an additional award over three years for a Phase 3 study of brivoligide. Adynxx has studied brivoligide to date using total knee arthroplasty (TKA) as a surgical model, and this grant allows a broader evaluation of brivoligide in soft-tissue surgeries such as mastectomy.

"This award to Adynxx is recognition of the need to not only provide a non-abusable method to reduce postoperative pain, but also to reduce postoperative opioid utilization in a population of patients who experience increased and prolonged pain and are relatively insensitive to analgesics," said Dr. Donald C. Manning, MD, PhD, Adynxx Chief Medical Officer and Co-Primary Investigator. "We look forward to rapidly advancing brivoligide toward approval and commercialization to provide a much needed therapy for postoperative pain that can also reduce the need for opioids."

“This grant is further validation of Adynxx’s novel approach to reducing long-term postoperative pain with the goal of dramatically reducing the need for opioid-based therapies specifically in those patients at the greatest risk of suffering increased and prolonged pain,” added Dennis Podlesak, Adynxx Chairman and Partner of Domain Associates. “Additionally, we believe brivolidide can fundamentally transform the treatment of postoperative pain and help address the national opioid crisis.”

About Adynxx

Adynxx is a clinical stage biopharmaceutical company focused on bringing to market novel, disease-modifying products for the treatment of pain and inflammation. Since its founding in 2007, Adynxx has worked to discover and develop transcription factor decoys to modify the course of pain. Adynxx’s resulting pipeline includes brivolidide, a Phase 2 drug candidate intended to address postoperative pain in a readily-identified group of patients with a greater risk of experiencing increased pain and elevated opioid use following surgery, and AYY2, a pre-clinical candidate intended to treat chronic syndromes of pain, including both inflammatory and neuropathic pain. Both programs were discovered by Adynxx and are part of the AYY decoy technology platform. Adynxx plans to continue development of brivolidide and AYY2, plans to collaborate with twoXAR to use twoXAR’s artificial intelligence-driven drug discovery platform to identify endometriosis treatments, and also seeks to identify potential in-licensing opportunities to build a pipeline of complementary product candidates in pain and inflammation. For more information, visit www.adynxx.com.

About Brivolidide

Brivolidide (formerly AYY1) is an intrathecally-administered, 23 base-pair, double-stranded DNA transcription factor decoy oligonucleotide. It inhibits the transcription factor EGR1 in the dorsal root ganglia (“DRG”) and spinal cord at the time of surgery. EGR1 binds to the promoter regions of many genes associated with nociceptive sensitization and increased pain. EGR1 launches waves of gene regulation at the time of surgery that initiate and maintain neuronal sensitization. This sensitization may lead to increased and prolonged postoperative pain in certain patients, who are relatively insensitive to analgesics and may be at high risk for elevated use of rapidly acting opioids, the type most commonly associated with opioid use disorders. These patients are readily identified using the PCS and represent approximately one third of the surgical population. To date, brivolidide has been evaluated in four clinical studies: a Phase 1 safety study in healthy volunteers (ADYX-001) and three Phase 2 studies in subjects undergoing TKA (ADYX-002, -003 and -004).

Forward-Looking Statements

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