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): **November 12, 2019**

Adynxx, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-36278**	**58-2349413**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

100 Pine Street, Suite 500
San Francisco, California 94111
(Address of principal executive offices) (Zip Code)

(Registrant's telephone number, including area code): **(415) 512-7740**

N/A
(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 obligations 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.001 per share	**ADYX (OTCQB)**	**N/A**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter):

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 2.02. Results of Operations and Financial Condition.

On November 14, 2019, Adynxx, Inc. announced its financial results for the quarter ended September 30, 2019. This press release, which is attached hereto as Exhibit 99.1, is incorporated herein by reference.

The information in this Item 2.02, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities of that Section, and shall not be deemed incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, except as expressly stated by specific reference in such filing.

Item 4.02 Non-Reliance on Previously Issued Financial Statements or a Related Audit Report or Completed Interim Review.

(a)

On November 14, 2019, we filed an amendment to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, as filed with the Securities and Exchange Commission on August 14, 2019, on Form 10-Q/A. The Form 10-Q/A was filed to correct an inadvertent error in our consolidated statements of operations for the three and six months ended June 30, 2019 and 2018 that was identified by management following the filing of the original Quarterly Report on Form 10-Q, during the course of our review of our weighted average shares outstanding. In the original Quarterly Report on Form 10-Q, we incorrectly overstated the weighted average number of shares outstanding as of June 30, 2019 and 2018 by including the mandatory conversion of preferred stock into common stock upon completion of our reverse merger with Alliqua BioMedical, Inc. retroactively instead of prospectively. As a result, we understated the amounts of net loss per diluted share for the three and six months ended June 30, 2019 and 2018.

On November 12, 2019, our President and Chief Executive Officer, our Senior Vice President, Finance, and the audit committee of our board of directors, concluded that the consolidated statements of operations for the three and six months ended June 30, 2019 and 2018, as reported in the original Quarterly Report on Form 10-Q filed on August 14, 2019, should not be relied upon because of the error described above, which has been corrected in the Form 10-Q/A filed on November 14, 2019. We also discussed this assessment with our independent registered public accounting firm BDO USA, LLP.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit	Description
99.1	Press Release, dated November 14, 2019.

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.

ADYNXX, INC.

Dated: November 14, 2019

By: /s/ Rick Orr
Name: Rick Orr
Title: President and Chief Executive Officer

Exhibit 99.1

Adynxx Reports Third Quarter 2019 Financial Results

SAN FRANCISCO (GLOBE NEWSWIRE)— November 14, 2019 – Adynxx, Inc. (OTCQB: ADYX), a clinical-stage biopharmaceutical company focused on the development of transcription factor decoy technology and first-in-class therapeutics for the treatment of pain and inflammatory diseases, today announced financial results and provided a business update for the quarter ended September 30, 2019.

"We believe the recent grant from the National Institute on Neurological Disease and Stroke (NINDS), part of the National Institutes of Health (NIH), to support development of our second product candidate, AYX2 for chronic pain, serves as additional validation of the therapeutic potential of our AYX platform of transcription factor decoys," said Rick Orr, President and Chief Executive Officer of Adynxx. "We look forward to further advancing our portfolio of non-opioid pain therapies and helping to combat the ongoing opioid crisis with potentially improved, non-addictive treatments for pain."

As previously announced, Adynxx received in December 2018 an award from the National Institute on Drug Abuse (NIDA), part of the NIH, for up to $15 million to support clinical development of its lead program, brivoligide, which is being studied in Phase 2 clinical trials for postoperative pain. Both awards are part of the Helping to End Addiction Long-term, or the NIH HEAL Initiative, which aims to improve treatments for chronic pain, curb the rates of opioid use disorder and overdose, and achieve long-term recovery from opioid addiction.

Business Highlights and Recent Developments

- Received a Notice of Award for $602,516 from NINDS, part of the NIH, to support development of AYX2, Adynxx's product candidate intended to treat chronic pain.

- Continued activities toward initiation of one to two Phase 2 studies of brivoligide as early as the first quarter of 2020:

    - ADYX-006 is a Phase 2 randomized double-blind, placebo-controlled study to evaluate the safety and efficacy of a single intrathecal preoperative administration of brivoligide injection in patients with a PCS score ≥16 undergoing mastectomy. Adynxx plans to commence this Phase 2 clinical trial as early as the first quarter of 2020, with top-line results expected as early as the first half of 2021, subject to receipt of additional funds from a grant award from NIDA (the "NIDA Grant") for $5.7 million over a two-year period to complete ADYX-006 and receipt of additional capital to fund the trial through top-line results. Following completion of milestones related to ADYX-006, Adynxx can receive an additional award of up to $9 million for a Phase 3 study of brivoligide.

- ADYX-005 is a Phase 2 randomized double-blind, placebo-controlled study to evaluate the safety and efficacy of a single intrathecal preoperative administration of brivoligide injection in patients with a PCS score ≥16 undergoing total knee arthroplasty. Adynxx is evaluating whether to commence this Phase 2 clinical trial as early as the first quarter of 2020. If that is the timing, Adynxx expects top-line results as early as the fourth quarter of 2020, subject to receipt of additional capital to fund the trial through top-line results.

- Under the collaboration agreement with twoXAR, Adynxx continued evaluation of potential product candidates to determine if any are viable for further development.

Financial Results

Adynxx reported a net loss of $1.9 million for the third quarter of 2019, compared to a net loss of $1.5 million for the same period in 2018.

Research and development expenses were $2.0 million in the third quarter of 2019, compared to $0.5 million for the same period in 2018. The increase was primarily due to $1.0 million in connection with start-up activities related to Adynxx's planned Phase 2 ADYX-005 TKA and the Phase 2 ADYX-006 mastectomy clinical trials and $0.6 million related to the initiation of drug supply manufacturing with Avecia, partially offset by a $0.1 million reduction in salaries and benefits from the resignation of an employee and other minor cost changes.

General and administrative expenses were $1.0 million in the third quarter of 2019, compared to $0.8 million for the same period in 2018. The increase was primarily due to $0.2 million in other general and administrative costs, including insurance, associated with Adynxx being a public company.

Interest expense was $0.2 million in the third quarter of 2019, compared to $0.3 million for the same period in 2018. This decrease was primarily due to extinguishment of debt discount upon modification of debt terms.

As of September 30, 2019, Adynxx had $331,000 in cash and cash equivalents, term loans, including accrued interest, of $3.0 million from Oxford Finance, LLC, and $6.6 million aggregate principal amount of convertible promissory notes (the "Notes"), including accrued interest, outstanding. The Notes accrue interest at 8% per annum and mature on the first anniversary of the applicable issuance date.

During August 2019, Adynxx entered into an agreement to resolve a vendor dispute. The vendor agreed to pay Adynxx a settlement amount of $635,000 over a three-month period ending October 31, 2019. As of September 30, 2019, Adynxx has received $443,000 of the settlement amount.

Qualified expenses incurred and reimbursements received under the NIDA Grant for the third quarter of 2019 were $0.7 million.

About Adynxx

Adynxx is a clinical-stage biopharmaceutical company focused on bringing to market novel therapeutics for the treatment of pain and inflammatory diseases. A leader in transcription factor decoy technology, Adynxx is utilizing its platform of AYX transcription factor decoys to create first-in-class therapies with disease-modifying properties. Transcription factor decoys are short, synthetic double-stranded DNA oligonucleotides that bind to transcription factors and prevent their interaction with the genome, effectively inhibiting a coordinated network of pathologic gene expression. The AYX platform has applications across multiple disease states and has initially been leveraged to create novel, non-opioid therapeutics for the treatment of pain.

About Brivoligide

Clinical studies conducted to date indicate that a single administration of brivoligide at the time of surgery, in addition to standard of care, can reduce pain for weeks and accelerate the time to achieve mild pain. Brivoligide (formerly AYX1) 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 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 Disorder or OUD.

Forward-Looking Statements

Statements contained in this press release that are not purely historical may be deemed to be 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. Without limiting the foregoing, the use of words such as “may,” “intends,” “can,” “might,” “will,” “expect,” “plan,” and other similar expressions are intended to identify forward-looking statements. The product candidates discussed are in clinic and not approved and there can be no assurance that the clinical programs will be successful in demonstrating safety and/or efficacy, that Adynxx will not encounter problems or delays in clinical development, or that any product candidate will ever receive regulatory approval or be successfully commercialized. 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. In addition, Adynxx’s business is subject to additional risks and uncertainties, including among others, the initiation and conduct of preclinical studies and clinical trials; the timing and availability of data from preclinical studies and clinical trials; expectations for regulatory submissions and approvals; potential safety concerns related to, or efficacy of, Adynxx’s product candidates; the availability or commercial potential of product candidates; the ability of Adynxx to fund its continued operations, including its planned clinical trials; the ability of Adynxx to list its stock on a national securities exchange and maintain such listing; the availability of sufficient drug product for Adynxx to conduct clinical trials in a timely manner; and Adynxx’s and its partners’ ability to perform under their license, collaboration and manufacturing arrangements. These statements are also subject to a number of material risks and uncertainties that are described in the Quarterly Report on Form 10-Q filed by Adynxx, Inc. with the Securities and Exchange Commission on November 14, 2019, as updated by Adynxx’s subsequent filings with the Securities and Exchange Commission. 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 under applicable law.

Adynxx, Inc. (formerly Alliqua Biomedical, Inc.)
Condensed Consolidated Statements of Operations

(In thousands, except share and per share data) (Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Operating expenses				
Research and development	$ 1,986	$ 524	$ 5,212	$ 1,793
General and administrative	1,037	810	3,354	2,102
Grant reimbursements	(716)	-	(1,914)	-
Gain on settlement	(635)	-	(635)	-
Total operating expenses, net	1,672	1,334	6,017	3,895
Loss from operations	(1,672)	(1,334)	(6,017)	(3,895)
Interest expense, net	(223)	(322)	(2,864)	(767)
Other income (expense), net	-	151	(94)	211
Loss from continuing operations	(1,895)	(1,505)	(8,975)	(4,451)
Loss from discontinued operations	-	-	(58)	-
Net loss	$ (1,895)	$ (1,505)	$ (9,033)	$ (4,451)
Net loss per basic and diluted share:				
Loss from continuing operations	$ (0.33)	$ (2.14)	$ (2.56)	$ (6.34)
Loss from discontinued operations	-	-	(0.02)	-
Net loss per basic and diluted share	$ (0.33)	$ (2.14)	$ (2.58)	$ (6.34)
Weighted-average number of common shares outstanding - basic and diluted	5,807,877	701,808	3,507,338	701,808

Adynxx, Inc. (formerly Alliqua Biomedical, Inc.)
Condensed Consolidated Balance Sheets

(In thousands, except share and per share data)

	September 30, 2019 (unaudited)	December 31, 2018
Cash and cash equivalents	$ 331	$ 1,887
Total assets	3,254	1,980
Total liabilities	14,316	9,800
Total convertible redeemable preferred stock	-	28,711
Total stockholders' deficit	(11,062)	(36,531)

View source version on https://ir.adynxx.com/press-releases

Source: Adynxx, Inc.

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