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): **August 14, 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 August 14, 2019, Adynxx, Inc. announced its financial results for the quarter ended June 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 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, or the Securities Exchange Act of 1934, as amended, except as expressly stated by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit	Description
99.1	Press Release, dated August 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: August 14, 2019

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

Exhibit 99.1

Adynxx Reports Second Quarter 2019 Financial Results

SAN FRANCISCO, Aug. 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 second quarter ended June 30, 2019.

"The second quarter of 2019 was transformative for Adynxx as we completed our merger with Alliqua BioMedical to become a public company," said Rick Orr, President and Chief Executive Officer of Adynxx. "We are focused on continuing to advance brivoligide, our lead product candidate for post-operative pain, as well as our discovery and development activities related to additional product candidates. In the near-term we intend to initiate one to two Phase 2 studies of brivoligide this year, one of which is funded with the support of the National Institute on Drug Abuse (NIDA), part of the National Institutes of Health (NIH). We are also actively and diligently pursuing a path to comply with the requirements to list our shares on a U.S. stock exchange. We believe we remain on track with our business initiatives."

Business Highlights and Recent Developments

- Continued activities to initiate one to two Phase 2 studies of brivoligide in the second half of 2019:
    - ADYX-006, 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 fourth quarter of 2019, with top-line results expected as early as the second half of 2020, subject to receipt of additional funds from a grant award from NIDA for $5.7 million over a two-year period to complete ADYX-006. 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 fourth quarter of 2019, with top-line results expected as early as the second half of 2020, subject to receipt of additional capital to fund the trial through top-line results.

- Appointed Matthew Ruth and Gregory J. Flesher to the Board of Directors, bringing to the Adynxx Board additional experience in the building of successful life science companies, getting novel drugs approved and growing companies to acquisitions by larger pharmaceutical companies.

- Under the collaboration agreement with twoXAR, received initial candidate predictions from twoXAR's proprietary artificial-intelligence based drug discovery platform of potential novel drug candidates for the treatment of endometriosis; subsequently initiated a review of the potential product candidates to determine if any are viable candidates for further R&D development.

- Continued evaluating equity financing options to, among other things, satisfy the listing requirements of a U.S. national securities exchange.

- Completed certain actions initiated and declared by Alliqua BioMedical, Inc., our predecessor company, including payment of a previously announced special cash dividend and distribution of all shares of AquaMed Technologies, Inc., formerly a wholly owned subsidiary of Alliqua, to record holders of Alliqua.

- Completed the merger with Alliqua BioMedical, Inc., with the combined organization's shares currently quoted on the OTCQB market (OTCQB) under the ticker "ADYX."

Financial Results

Adynxx reported a net loss of $4.7 million for the second quarter of 2019, compared to a net loss of $1.4 million for the same period in 2018.

Research and development expenses were $1.9 million in the second quarter of 2019, compared to $0.6 million for the same period in 2018. The increase was primarily due to $0.7 million in connection with start-up activities related to our planned Phase 2 ADYX-005 total knee arthroplasty and Phase 2 ADYX-006 mastectomy clinical trials and $0.7 million related to the initiation of drug supply manufacturing with Avecia, partially offset by a reduction in salaries and benefits from the resignation of an employee and other minor cost changes.

General and administrative expenses were $1.5 million in the second quarter of 2019, compared to $0.6 million for the same period in 2018. The increase was primarily due to $0.7 million in legal and professional service costs incurred in connection with the merger with Alliqua BioMedical and preparation to be a public company, and an increase of $0.2 million in other general and administrative costs, including insurance, associated with us being a public company.

Interest expense was $2.4 million in the second quarter of 2019, compared to $0.3 million for the same period in 2018. The increase was primarily due to the recognition of $2.1 million associated with the beneficial conversion feature recognized upon the modification and conversion of $3.0 million of principal amount of certain notes in connection with the merger with Alliqua BioMedical

As of June 30, 2019, the Company had $24,000 in cash and cash equivalents, term loans, including accrued interest, of $3.0 million from Oxford Finance, LLC, and $5.6 million aggregate principal amount of convertible promissory notes (the "Notes"), including accrued interest, outstanding. In July 2019, the Company issued $0.6 million principal amount of additional Notes to existing noteholders. The Notes accrue interest at 8% per annum and mature on the first anniversary of the applicable issuance date.

In December 2018, the Company received a Notice of Award from the National Institute on Drug Abuse ("NIDA"), part of the National Institutes of Health ("NIH"), to support the clinical development of its lead product candidate, brivoligide. NIH grants provide funds for certain types of expenditures in connection with research and development activities over a contractually defined period. The maximum funding expected to be available under this grant for qualified expenditures over the two-year period through December 2020 is approximately $5.7 million. Qualified expenses incurred and reimbursements received under the grant for the second quarter of 2019 were $1.1 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 August 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 June 30,		Six months ended June 30,	
	2019	2018	2019	2018
Operating expenses				
Research and development	$ 1,895	$ 583	$ 3,226	$ 1,269
General and administrative	1,454	598	2,317	1,292
Grant reimbursements	(1,104)	-	(1,198)	-
Total operating expenses, net	2,245	1,181	4,345	2,561
Loss from operations	(2,245)	(1,181)	(4,345)	(2,561)
Interest expense, net	(2,373)	(301)	(2,641)	(445)
Other income (expense), net	-	60	(94)	60
Loss from continuing operations	(4,618)	(1,422)	(7,080)	(2,946)
Loss from discontinued operations	(58)	-	(58)	-
Net loss	$ (4,676)	$ (1,422)	$ (7,138)	$ (2,946)
Net loss per basic and diluted share:				
Loss from continuing operations	$ (0.86)	$ (0.31)	$ (1.43)	$ (0.64)
Loss from discontinued operations	(0.01)	-	(0.01)	-
Net loss per basic and diluted share	$ (0.87)	$ (0.31)	$ (1.44)	$ (0.64)
Weighted-average number of common shares outstanding - basic and diluted	5,358,882	4,569,742	4,966,491	4,569,742

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

(In thousands, except share and per share data)

	June 30, 2019 (unaudited)	December 31, 2018
Cash and cash equivalents	$ 24	$ 1,887
Total assets	2,703	1,980
Total liabilities	11,954	9,800
Total convertible redeemable preferred stock	-	28,711
Total stockholders' deficit	(9,251)	(36,531)

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

Source: Adynxx, Inc.

Investors:
Patti Bank
Managing Director
Westwicke, an ICR company
(415) 513-1284
patti.bank@westwicke.com

Media:
David Schull
President
Russo Partners
(858) 717-2310
david.schull@russopartnersllc.com