

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT**  
**Pursuant to Section 13 or 15(d)**  
**of the Securities Exchange Act of 1934**  
Date of Report (Date of earliest event reported): **October 2, 2019**

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**Adynxx, Inc.**  
(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-36278**  
(Commission  
File Number)

**58-2349413**  
(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)

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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 |
|--|-------------------------|---|
| <b>Common stock, par value \$0.001 per share</b> | <b>ADYX<br/>(OTCQB)</b> | <b>N/A</b>                                |

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.

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**Item 7.01. Regulation FD Disclosure.**

On October 2, 2019, Adynxx, Inc. announced the receipt of a Notice of Award from the National Institute on Neurological Disease and Stroke, part of the National Institutes of Health. This press release, which is attached hereto as Exhibit 99.1, is incorporated herein by reference.

The information in this Item 7.01, 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, or the Securities Act, except as expressly stated by specific reference in such filing.

**Item 9.01. Financial Statements and Exhibits.**

**(d) Exhibits.**

| <u>Exhibit</u> | <u>Description</u>                                    |
|----------------|---|
| 99.1           | <a href="#">Press Release, dated October 2, 2019.</a> |

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**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: October 2, 2019

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



**Adynxx Receives NIH HEAL Initiative Funding Award  
for Development of Second Non-Opioid Pain Therapeutic**

*Award of More than \$600K Will Support Advancement of  
AYX2 for Chronic Pain to IND-Enabling Studies*

SAN FRANCISCO, Calif., October 2, 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 the receipt of a Notice of Award for \$602,516 from the National Institute on Neurological Disease and Stroke (NINDS), part of the National Institutes of Health (NIH), to support development of AYX2, the company's product candidate intended to treat chronic pain. As previously announced, in December 2018 Adynxx received 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, brivolidge, 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. For further information about the NIH HEAL Initiative and the grant awards please visit: <https://heal.nih.gov>

"It's clear that a multi-pronged scientific approach is needed to reduce the risks of opioids, accelerate development of effective non-opioid therapies for pain and provide more flexible and effective options for treating addiction to opioids," said NIH Director Francis S. Collins, M.D., Ph.D., who launched the initiative in early 2018. "This unprecedented investment in the NIH HEAL Initiative demonstrates the commitment to reversing this devastating crisis."

AYX2 is a non-opioid product candidate in development for the treatment of chronic pain resulting from multiple causes or origins, including inflammatory pain and neuropathic pain. The second product candidate originating from the Adynxx AYX platform, AYX2 is a transcription factor decoy targeting the activity of specific members of the Krüppel-like (KLF) family of transcription factors: KLF6, KLF9 and KLF15. Adynxx has published non-clinical work showing that KLF6, KLF9 and KLF15 transcription factors cooperate to maintain chronic pain and that a single administration of AYX2 can potentially provide long-term pain relief.

"We are grateful for the recognition of the therapeutic potential of our platform of non-opioid decoys with this second award from NIH," said Julien Mamet, Ph.D., founder and Chief Scientific Officer of Adynxx and Primary Investigator on the funding award. "We believe AYX2 could transform the treatment of chronic pain and potentially provide long-term relief with a single or short-term treatment. We are excited to be part of the NIH HEAL initiative and appreciate the support of NINDS on this novel approach to reducing chronic pain."

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## **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.

## **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; 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 Adynxx’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2019 filed 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.

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

Source: Adynxx, Inc.

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