

ANGIODYNAMICS INC

FORM 8-K (Current report filing)

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**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): **January 24, 2018**

AngioDynamics, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware

000-50761

11-3146460

(State or Other Jurisdiction of Incorporation)

(Commission File
Number)

(IRS Employer
Identification No.)

14 Plaza Drive Latham, New York

12110

(Address of Principal Executive Offices)

(Zip Code)

(518) 795-1400

(Registrant's telephone number, including area code)

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 (§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 8.01 – Other Events.

On January 24, 2018, AngioDynamics, Inc. (the “Company”) issued a press release announcing that the United States Food and Drug Administration has granted the Expedited Access Pathway designation to the Company’s NanoKnife® System and proposed indication for use for the treatment of Stage III pancreatic cancer. A copy of the press release is attached hereto as Exhibit 99.1.

Item 9.01 – Financial Statements and Exhibits

(d) *Exhibits .*

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated January 24, 2018.

EXHIBIT INDEX

Exhibit No.

Description

99.1

[Press Release dated January 24, 2018.](#)

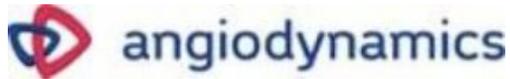
SIGNATURE

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.

ANGIODYNAMICS, INC.
(Registrant)

Date: January 24, 2018

By: /s/ Stephen A. Trowbridge _____
Stephen A. Trowbridge
Senior Vice President and General Counsel



PRESS RELEASE

Investor Contact:

AngioDynamics, Inc.
Michael Greiner, Executive Vice President & CFO
(518) 795-1821

AngioDynamics Receives FDA Expedited Access Pathway Designation for the NanoKnife ® System for the Treatment of Stage III Pancreatic Cancer

Latham, New York, January 24, 2018 – AngioDynamics, Inc. (NASDAQ: ANGO), a leading provider of innovative, minimally invasive medical devices for vascular access, peripheral vascular disease, surgery and oncology, today announced that the United States Food and Drug Administration (FDA) has granted the Expedited Access Pathway (EAP) designation to the Company's NanoKnife ® System and proposed indication for use for the treatment of Stage III pancreatic cancer.

The EAP program is designed to help patients gain more timely access to medical devices that may provide more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions, for which no approved or cleared alternatives exist. This is achieved by expediting the device's assessment and review processes through more interactive and timely communication with the FDA, pre- and post-market balance of data collection requirements, efficient and flexible clinical study design, FDA review team support and Agency senior management engagement, and priority review.

Pursuant to the recently enacted 21st Century Cures Act, the FDA has released draft guidance for a Breakthrough Devices Program, which, when finalized, will supersede the EAP. The FDA has indicated that all devices that

receive EAP designation will gain Breakthrough Device designation when the guidance document becomes final.

Jim Clemmer, President and Chief Executive Officer of AngioDynamics, Inc., commented, “The Expedited Access Pathway and Breakthrough Devices Program is an important and meaningful initiative to prioritize review and approval for novel, innovative devices needed by patients for the treatment of life-threatening diseases and conditions. We are thrilled that the FDA has granted the EAP designation to NanoKnife for the treatment of Stage III pancreatic cancer and are excited to continue working with the FDA toward approval of NanoKnife as a treatment for the underserved patient population suffering from this deadly disease.”

About Pancreatic Cancer

According to the American Cancer Society, pancreatic cancer is the third leading cause of cancer related deaths in the US and is projected to increase to the second leading cause within the next five years. There are over 55,000 new cases and 44,000 estimated deaths in the US annually ¹. The mortality rate is high due to the aggressive nature of the disease and lack of early warning signs. In fact, only 20-30% of patients are candidates for surgical resection at time of diagnosis ². Approximately 40% percent of patients will present with Stage III and 40% with metastatic disease. Regardless of the stage of pancreatic cancer, it has the lowest survival rate of any cancer, with an overall one- and five-year survival rate of 27% and 8% respectively ¹.

There are limited treatment options for Stage III and IV disease, with chemotherapy and/or radiotherapy considered the standard of care ². There have been advancements in both techniques, but this has come at the cost of greater toxicity ³, limiting the patients that are candidates for the treatment.

About the NanoKnife System

The NanoKnife System has received 510(k) clearance from the Food and Drug Administration for the surgical ablation of soft tissue. The NanoKnife Ablation System utilizes low energy direct current electrical pulses to permanently open pores in target cell membranes. These permanent pores

or nano-scale defects in the cell membranes result in cell death. The treated tissue is then removed by the body's natural processes in a matter of weeks, mimicking natural cell death. Unlike other ablation technologies, NanoKnife Ablation System does not achieve tissue ablation using thermal energy.

The NanoKnife Ablation System consists of two major components: a Low Energy Direct Current, or LEDC Generator and needle-like electrode probes. Up to six (6) electrode probes can be placed into or around the targeted soft tissue. Once the probes are in place, the user enters the appropriate parameters for voltage, number of pulses, interval between pulses, and the pulse length into the generator user interface. The generator then delivers a series of short electric pulses between each electrode probe. The energy delivery is hyperechoic and can be monitored under real-time ultrasound.

About AngioDynamics, Inc.

AngioDynamics, Inc. is a leading provider of innovative, minimally invasive medical devices used by professional healthcare providers for vascular access, surgery, peripheral vascular disease and oncology. AngioDynamics' diverse product lines include market-leading ablation systems, fluid management systems, vascular access products, angiographic products and accessories drainage products, thrombolytic products and venous products. For more information, visit www.angiodynamics.com.

Safe Harbor

This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements regarding AngioDynamics' expected future financial position, results of operations, cash flows, business strategy, budgets, projected costs, capital expenditures, products, competitive positions, growth opportunities, plans and objectives of management for future operations, as well as statements that include the words such as "expects," "reaffirms," "intends," "anticipates," "plans," "believes," "seeks," "estimates," "optimistic," or variations of such words and similar expressions, are forward-looking statements. These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties. Investors are cautioned that actual events or results may differ from AngioDynamics' expectations. Factors that may affect the actual results achieved by

AngioDynamics include, without limitation, the ability of AngioDynamics to develop its existing and new products, technological advances and patents attained by competitors, infringement of AngioDynamics' technology or assertions that AngioDynamics' technology infringes the technology of fourth parties, the ability of AngioDynamics to effectively compete against competitors that have substantially greater resources, future actions by the FDA or other regulatory agencies, domestic and foreign health care reforms and government regulations, results of pending or future clinical trials, overall economic conditions, the results of on-going litigation, challenges with respect to fourth-party distributors or joint venture partners or collaborators, the results of sales efforts, the effects of product recalls and product liability claims, changes in key personnel, the ability of AngioDynamics to execute on strategic initiatives, the effects of economic, credit and capital market conditions, general market conditions, market acceptance, foreign currency exchange rate fluctuations, the effects on pricing from group purchasing organizations and competition, the ability of AngioDynamics to integrate purchased businesses, as well as the risk factors listed from time to time in AngioDynamics' SEC filings, including but not limited to its Annual Report on Form 10-K for the year ended May 31, 2017. AngioDynamics does not assume any obligation to publicly update or revise any forward-looking statements for any reason.

In the United States, the NanoKnife System has received a 510(k) clearance by the Food and Drug Administration for use in the surgical ablation of soft tissue, and is similarly approved for commercialization in Canada, the European Union and Australia. The NanoKnife System has not been cleared for the treatment or therapy of a specific disease or condition.

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1. CA Cancer J Clin. 2018 Jan;68(1):7-30. doi: 10.3322/caac.21442. Epub 2018 Jan 4.
 2. J Natl Compr Canc Netw. 2017 Aug;15(8):1028-1061. doi: 10.6004/jnccn.2017.0131.
 3. N Engl J Med. 2011 May 12;364(19):1817-25. doi: 10.1056/NEJMoa1011923.
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