

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): **March 9, 2021**

AngioDynamics, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

000-50761
(Commission File
Number)

11-3146460
(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))

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.01 per share	ANGO	NASDAQ Global Select Market

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 7.01 – Regulation FD Disclosure.

On March 9, 2021, James C. Clemmer, President and Chief Executive Officer of AngioDynamics, Inc. (“AngioDynamics”), and Stephen A. Trowbridge, Executive Vice President and Chief Financial Officer of AngioDynamics, will present at the Barclays Global Healthcare Conference. The presentation slides are furnished herewith as Exhibit 99.1.

The presentation slides furnished pursuant to Item 7.01 of this Form 8-K (including Exhibit 99.1) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities under that Section. Furthermore, the presentation slides shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act.

Forward-Looking Statements

This document and its attachments contain 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 scale and scope of the COVID-19 global pandemic, 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 third 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 third-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, 2020 and its Quarterly Reports on Form 10-Q for the fiscal periods ended August 31, 2020 and November 30, 2020. AngioDynamics does not assume any obligation to publicly update or revise any forward-looking statements for any reason.

Item 9.01 – Financial Statements and Exhibits.

(d) *Exhibits.*

Exhibit No. Description

[99.1](#) [Presentation slides for the Barclays Global Healthcare Conference, dated March 9, 2021](#)

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: March 9, 2021

By: /s/ Stephen A. Trowbridge
Name: Stephen A. Trowbridge
Title: Executive Vice President and Chief
Financial Officer

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ANGIODYNAMICS

Barclays Global Healthcare Conference

Jim Clemmer, President & CEO
Stephen Trowbridge, EVP & CFO



Forward-Looking Statement

Notice Regarding Forward-Looking Statements

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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.

Notice Regarding Non-GAAP Financial Measures

Management uses non-GAAP measures to establish operational goals and believes that non-GAAP measures may assist investors in analyzing the underlying trends in AngioDynamics' business over time. Investors should consider these non-GAAP measures in addition to, not as a substitute for or as superior to, financial reporting measures prepared in accordance with GAAP. In this presentation, AngioDynamics has reported adjusted EBITDA (income before interest, taxes, depreciation and amortization and stock-based compensation); adjusted net income, and adjusted earnings per share. Management uses these measures in its internal analysis and review of operational performance. Management believes that these measures provide investors with useful information in comparing AngioDynamics' performance over different periods. By using these non-GAAP measures, management believes that investors get a better picture of the performance of AngioDynamics' underlying business. Management encourages investors to review AngioDynamics' financial results prepared in accordance with GAAP to understand AngioDynamics' performance taking into account all relevant factors, including those that may only occur from time to time but have a material impact on AngioDynamics' financial results. Please see the tables that follow for a reconciliation of non-GAAP measures to measures prepared in accordance with GAAP.

ANGIODYNAMICS

Strategic Transformation



PURSUIT OF LARGER MARKETS

Active portfolio management enables us to compete in larger, growing markets relying on technology & innovation to produce measurable patient outcomes

FOCUSED RESOURCE DEVELOPMENT

Resource deployment is focused in areas that offer best opportunities for success

PORTFOLIO TRANSFORMATION

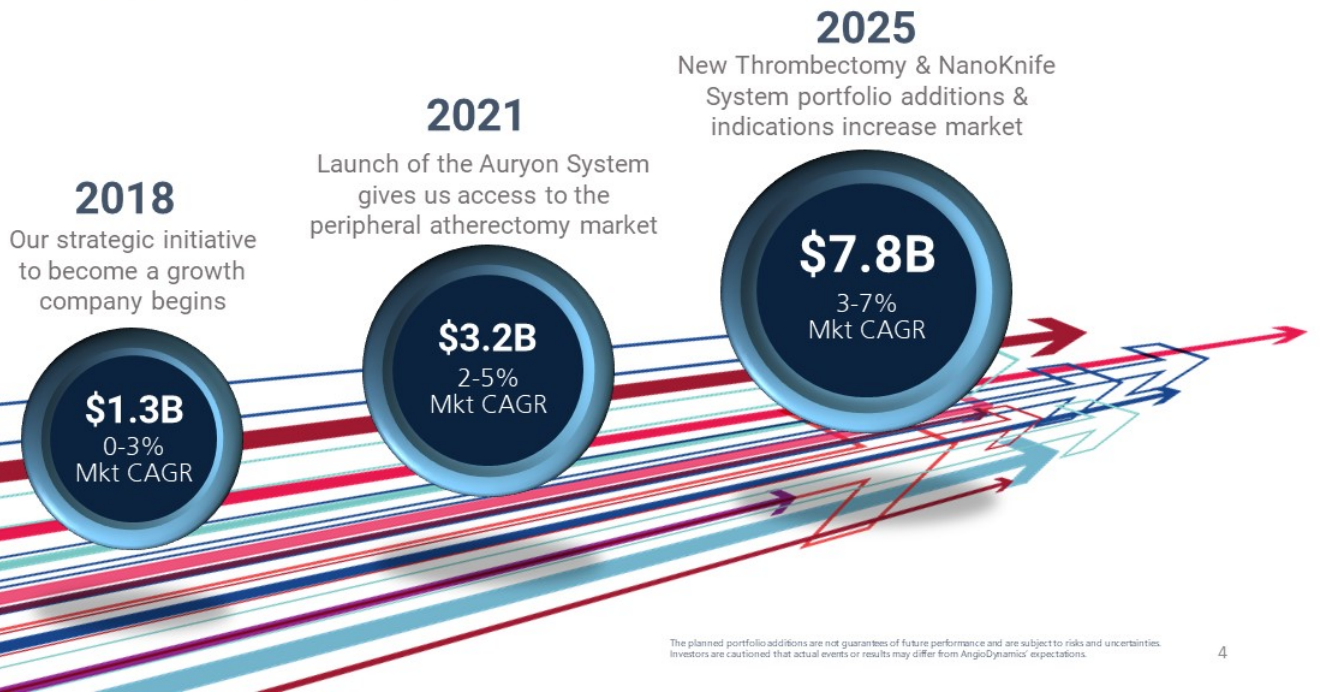
Portfolio transformation & strength is driven by R&D, M&A, and Clinical & Regulatory

TOP TALENT

Portfolio combined with talent drives value

FOCUSED TRANSFORMATION

U.S. Total Addressable Markets



The planned portfolio additions are not guarantees of future performance and are subject to risks and uncertainties. Investors are cautioned that actual events or results may differ from AngloDynamics' expectations.

INVEST FOR GROWTH

Peripheral Atherectomy

AURYON

Thrombus Management

AngioVac Uni-Fuse⁺

Irreversible Electroporation

NanoKnife 3.0

Irreversible Electroporation (IRE)



MAINTAIN POSITIONING

Vascular Access Catheters and Accessories

Diagnostic Catheters, Guidewires and Kits

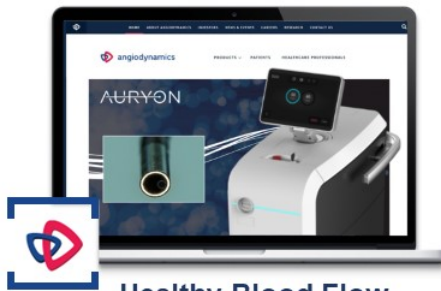
Endovenous Laser Treatment

Microwave & Radiofrequency Tumor Ablation

Lung Biopsy Safety

Radiation Treatment Stabilization Balloons

FOCUSED INVESTMENT



**Healthy Blood Flow
from the Heart**



**Healthy Blood Flow
to the Heart**



**Expanded Treatment
Options in Oncology**

Leveraging 3 main drivers to carve out our space in large, growing markets through innovative, disruptive technologies that treat patients with cancer, promote healthy blood flow and deliver critical therapies.

M & A

R & D

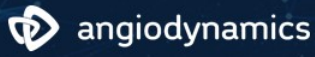
**Clinical and Regulatory Pathway
Expansion**



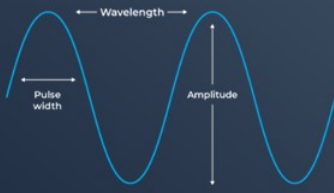
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PERIPHERAL ATHERECTOMY

AURYON



AURYON



2.35 mm
Aspiration and Off-Center capabilities^a for Peripheral Atherectomy and ISR and indicated for Peripheral Atherectomy and In-Stent Restenosis (ISR)

2.0 mm
Aspiration capability and indicated for Peripheral Atherectomy and ISR

1.5 mm
Indicated for Peripheral Atherectomy

0.9 mm
Indicated for Peripheral Atherectomy

Why wavelength matters

Each type of tissue interacts differently with a given wavelength

The Auryon System produces a photon energy of 3.5 eV, which is low enough to be nonreactive to vessel endothelium, but high enough to vaporize calcium.^{b,c}

Why pulse width and amplitude matter

Greater amplitude is achieved with shorter pulses, which can deposit energy before thermal diffusion occurs

The Auryon System has a pulse width of 10 to 25 ns, ensuring enough power to target the lesion and spare the vessel.^a

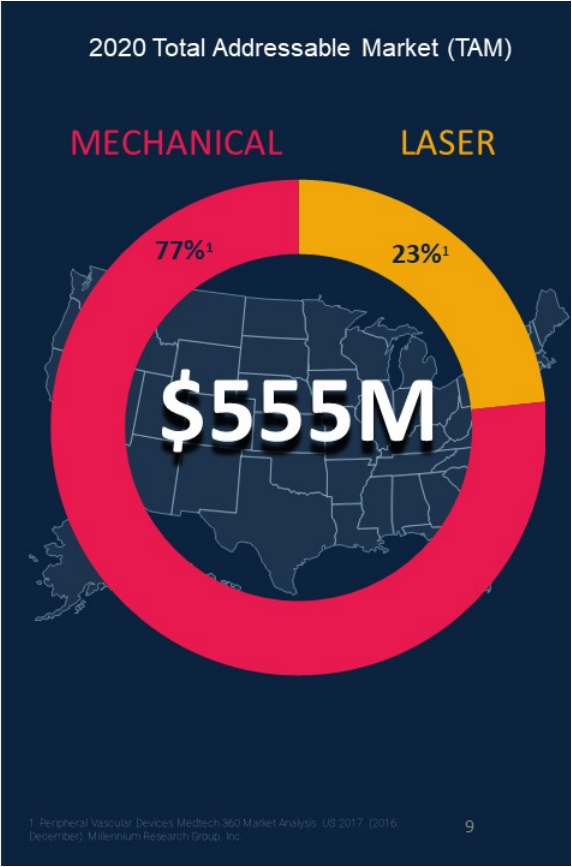


^a Auryon, Instructions for use, AngioDynamics, 2019.
^b Herzog A, Bogdan S, Gilkison M, Ishayya AA, Love C. Selective tissue ablation using laser radiation at 355 nm in lead extraction by a hybrid catheter, a preliminary report. *Lasers Surg Med.* 2016;48(3):281-287.
^c Spectranetics Corporation, DIVX-300 Excimer Laser System, Operator's Manual, Version 28, 2019:1-56.

PERIPHERAL ATHERECTOMY

US Addressable Markets & Competitive Landscape

Company	Product	Thrombus	Plaque	Fibrotic	ISR	Calcified
ANGO	Auryon	★★★★	★★★★	★★	★★★★	★★
Philips	Excimer Laser	★★	★★		★★★★	★
MDT	TurboHawk		★★★★	★		★
BSC	Jetstream	★★	★	★		
CSI	Diamondback 360		★★	★		★★★★



PERIPHERAL ATHERECTOMY

Continuing our momentum of growth

COMMERCIAL SCALE

- Targeted commercial & clinical expansion
- Meaningful physician training programs
- Increase physician ambassador programs



CLINICAL COMPENDIUM

- Expand awareness by creating a strong podium and clinical publication presence
- Clinically differentiated validation through new users, data collection (PATHFINDER I & II), and clinical outcomes



PRODUCT DEVELOPMENT

- Product development pipeline
- Portfolio and product indication expansion
- Continuous voice of customer

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THROMBUS MANAGEMENT

AngioVac | Uni-Fuse⁺

Deep Vein
Thrombosis

DVT

A blood clot that forms
in a deep vein, usually
the leg, groin or arm

**208,000 Iliofemoral
Cases¹**

Pulmonary
Embolism

PE

A DVT breaks free from a vein wall
and travels to the lungs, blocking
some or all of the blood supply

**171,000 High-risk & intermediate-risk
PE Cases¹**

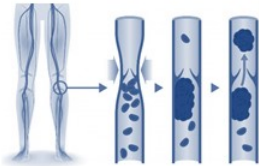
=

Venous
Thromboembolism

VTE

DVT and PE are collectively
referred to as VTE

**100,000 – 300,000 VTE-Related
Deaths in the USA Annually²**



Stages of Clot



Clot in Transit
(traveling through the heart)



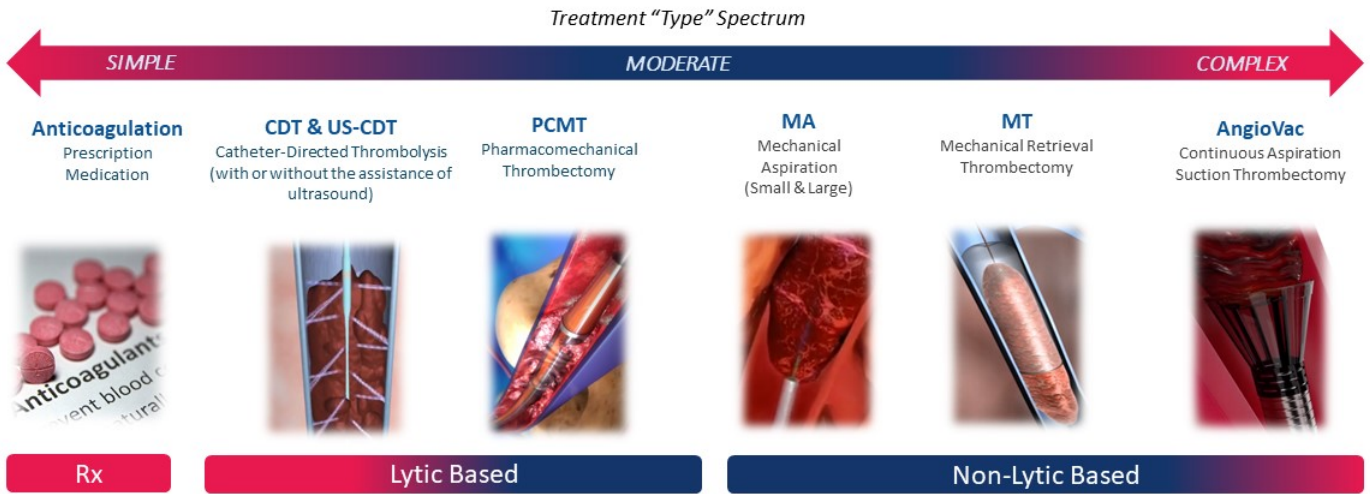
Clot in Pulmonary
Arteries (PE)



1. Piovanic, W. J., & Furlong, C. (2020, June). Inert Medical Biomedical Devices and Services. Canscofund Genuity Capital Markets.
2. "Venous Thromboembolism (VTE)." World Thrombosis Day. www.worldthromboticsday.org/faq/vte.
Illustrations and Images not Produced by AngioDynamics Include:
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC434924/>
DVT (Blood Clot in the Vein) | www.angiodynamics.com and www.angiodynamics.com/medical-health.com

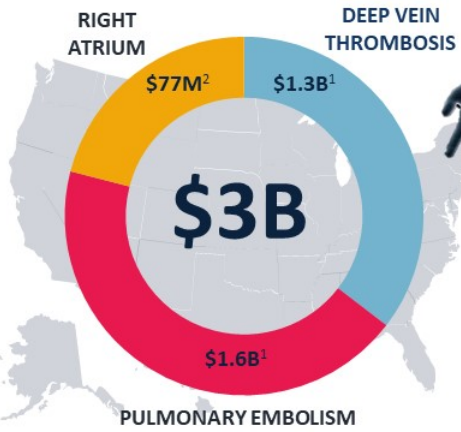
DVT & PE TREATMENT OPTIONS

Percutaneous Thrombectomy



THROMBUS MANAGEMENT

Purpose Built Portfolio & Technology



1. Plovnick, W. J., & Furlong, C. (2020, June). Inari Medical Biomedical Devices and Services. Canaccord Genuity Capital Markets.
2. Fletcher Spaght, Inc. AngioVac market assessment March 2018, Angiodynamics funded

CURRENT PORTFOLIO

Right Atrium | **AngioVac's** use is currently focused on the Right Atrium, which is a \$77M addressable market.

Planned Launch Calendar 2021

FUTURE PORTFOLIO

Pulmonary Embolism
Deep Vein Thrombosis

A multi-purpose mechanical aspiration device will allow us to compete in the broader DVT & PE addressable markets with a first-line treatment option without the need for perfusion.

CURRENT PORTFOLIO

DVT & PE | **Uni-Fuse+** catheter directed thrombolysis now has the additional indication for placement in the pulmonary artery.

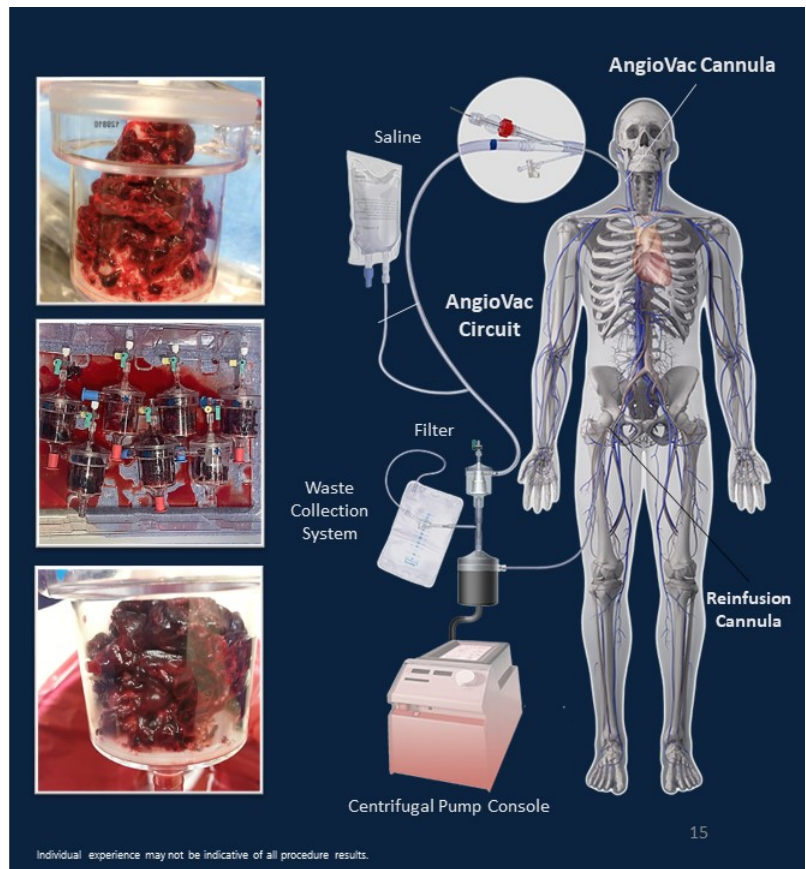


The AngioVac Difference

The AngioVac System allows for the **continuous aspiration** of embolic material such as fresh, soft thrombi or vegetation from the venous system

Utilizing a self-expanding, nitinol reinforced **funnel tip**

Simultaneously reinfusing the patient's own filtered blood to limit procedural blood loss



AngioVac Cannula

Saline

AngioVac Circuit

Filter

Waste Collection System

Centrifugal Pump Console

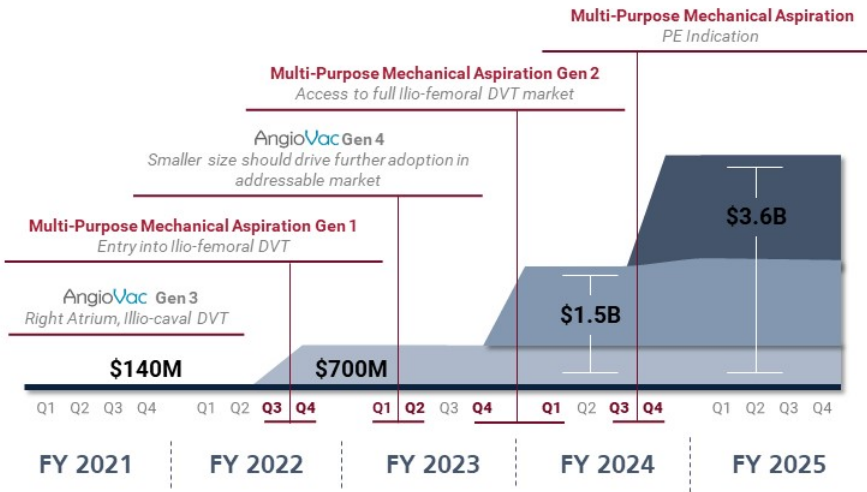
Reinfusion Cannula

15

Individual experience may not be indicative of all procedure results.

THROMBUS MANAGEMENT

Planned Portfolio Additions & U.S. Addressable Markets Expansion



The planned portfolio additions 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.

THE NEXT PORTFOLIO INNOVATION

A purpose-built, innovative product leveraging the strengths of the AngioVac cannula technology with *off-circuit* manual aspiration control



Powerful

Proven, funnel tip design allows efficient aspiration and compression of large clot burden



Controlled

Designed to allow the end-user command and control of the mechanical aspiration



Versatile

Broadens our Thrombus Management portfolio and designed to provide an intuitive, first-line treatment option without the need for lytics and advanced procedural support

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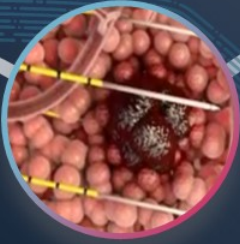
IRREVERSIBLE ELECTROPORATION

NanoKnife 3.0
Irreversible Electroporation (IRE)



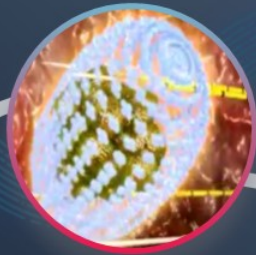
IRREVERSIBLE ELECTROPORATION

Non-thermal energy destroys cells while preserving critical structures



Probe placement

Placement of probes around a target area provides effective treatment coverage ^{a-d}



Electrical field

Electrical pulses cause pores to form within the cellular membrane leading to non-thermal cell death ^{a-d}



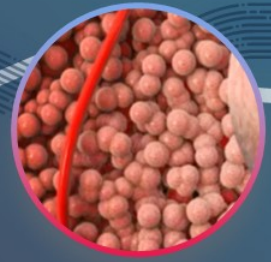
Decellularization

Target tissue undergoes complete decellularization while preserving the underlying structure of blood vessels, nerves, ducts, and tissue ^{a-d}



Non-thermal

By preserving those underlying structures the potential for revascularization of treated tissue is maintained ^{a-d}



Revascularization

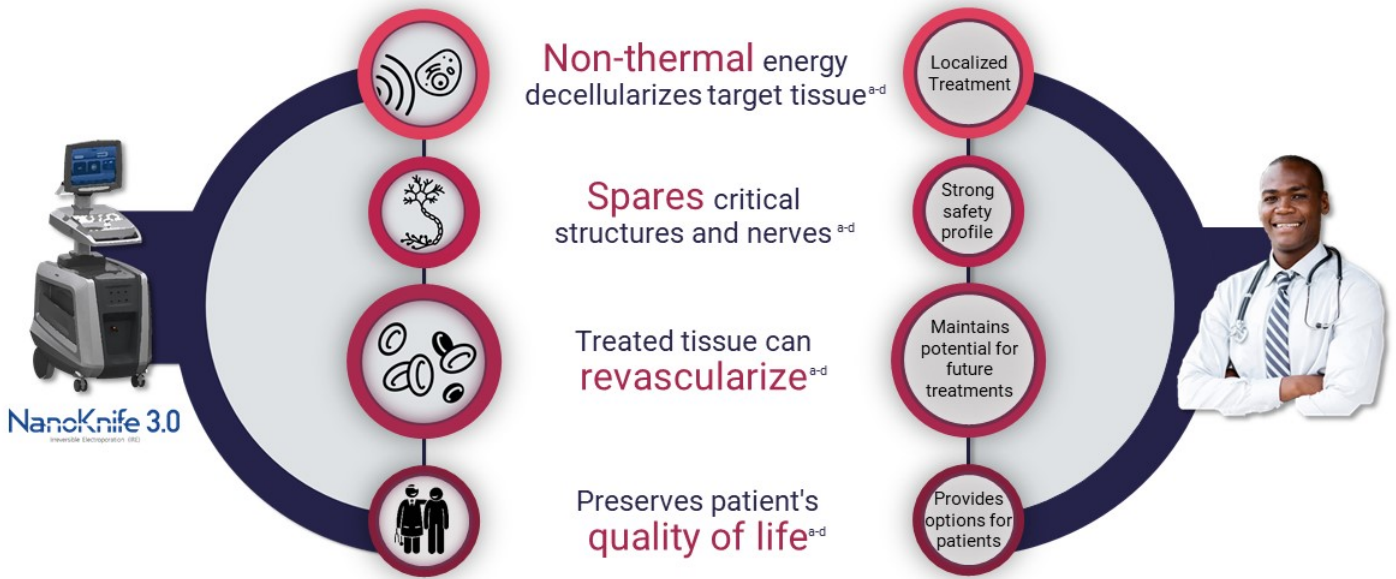
The NanoKnife System's unique technology enables physicians to provide localized treatments in locations and at times previously unavailable to them ^{a-d}



a. Maor E, et al., The effect of irreversible electroporation on blood vessels, *Technol. Cancer Res. Treat.*, 6(4), 307-312 (2007), 10.1177/15330346073060407.
b. Rubinsky B, Onik G, and Mikus P., Irreversible electroporation: a new ablation modality—clinical implications, *Technol. Cancer Res. Treat.*, 6, 27-48 (2007), doi:10.1177/15330346073060106.
c. Onik G, Mikus P., and Rubinsky B., Irreversible electroporation: implications for prostate ablation, *Technol. Cancer Res. Treat.*, 6(4), 295-300 (2007), 10.1177/15330346073060405.
d. Lee EW, Chen C, Prieto VE, Day SM, Joh CT, Vee ST. Advanced hepatic ablation technique for creating complete cell death: irreversible electroporation. *Radiology* 255:406-433, (2010). doi:1148/radiol.10090337

PROVIDES THE INNOVATION DOCTORS NEED

Expands treatment options and helps preserve patient's quality of life^{a-d}



NanoKnife 3.0
Irreversible Electroporation (IRE)

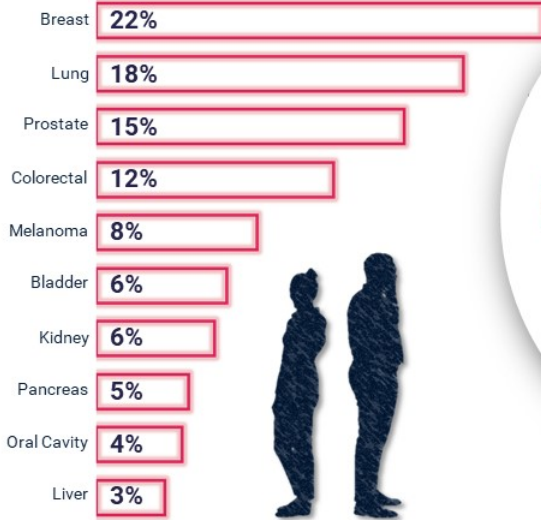
 **angiodynamics**

a. Macri E, et al. The effect of irreversible electroporation on blood vessels. *Technol. Cancer Res. Treat.* 6(4), 207-212 (2007). doi:10.1177/1522034607304047.
b. Rubinsky B, Onik G, and Mikus P. Irreversible electroporation: a new ablation modality-clinical implications. *Technol. Cancer Res. Treat.* 6, 27-49. (2007). doi:10.1177/152203460700600106.
c. Onik G, Mikus P, and Rubinsky B. Irreversible electroporation: implications for prostate ablation. *Technol. Cancer Res. Treat.* 6(4), 295-300 (2007). doi:10.1177/152203460700600405.
d. Lee EW, Chen C, Prieto VE, Dry SM, Loh CT, Kee ST. Advanced hepatic ablation technique for creating complete cell death: irreversible electroporation. *Radiology* 255:426-433. (2010). doi:10.1148/radiol.10090327

NanoKnife 3.0

Irreversible Electroporation (IRE)

New Cancer Cases 2020: 1,256,970 ^a



DIRECT Study

This study is evaluating the use of the NanoKnife System as a potential treatment for stage III pancreatic cancer.



Prostate IDE

This safety study will evaluate the use of the NanoKnife System as a focal therapy option for prostate tissue.

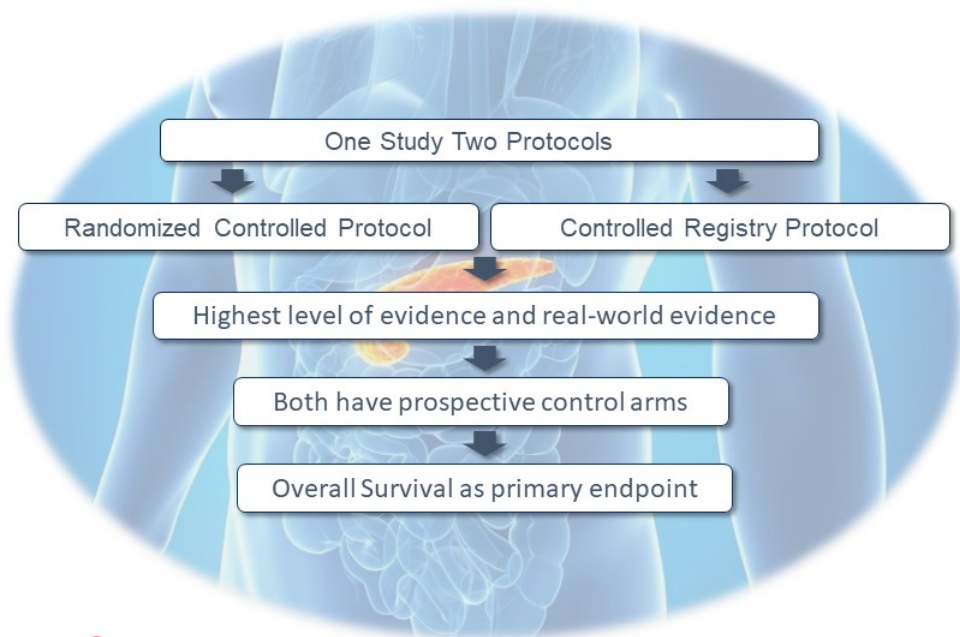


^a Cancer Facts & Figures 2020. American Cancer Society. <https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/cancer-facts-figures-2020.html>. Accessed January 7, 2021.

^b NanoKnife System. Angiodynamics. <http://www.angiodynamics.com>. Accessed January 7, 2021.

DIRECT STUDY

Data for IRE Cancer Treatment



CLINICAL EXPANSION

Within the U.S.
191,930 men will be diagnosed with prostate cancer in 2020.^a

27% will undergo radiotherapy of which **66%** report E.D. at 36 months^{b,c}



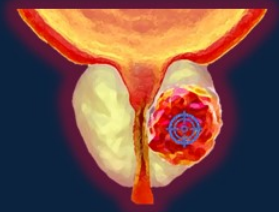
31% will undergo a radical prostatectomy of which **79%** report E.D. at 36 months^{b,c}



42% will undergo active surveillance^b



An estimated **38%** of these patients are ideal candidates for focal therapy^d



Focal therapy

bridges the gap between whole gland treatment and active surveillance in an attempt to **maximize quality of life** by avoiding the effects of whole gland radiation or surgery.

However... adoption remains low (**<5%**) due to gaps within existing technology.

^a Cancer Facts & Figures 2020. American Cancer Society. <https://www.cancer.org/research/amca-facts-figures/statistics/amca-facts-figures/cancer-facts-figures-2020.html>. Accessed January 7, 2021.
^b Hahn SA, Bicker S, Piantoni L, et al. Use of Active Surveillance or Watchful Waiting for Low-Risk Prostate Cancer and Management Trends Across Risk Groups in the United States, 2010-2015. *Jama*. 2019;321(7):704. doi:10.1001/jama.2018.19948
^c Donovan J. Patient-Reported Outcomes after Monitoring, Surgery, or Radiotherapy for Prostate Cancer. *The New England Journal of Medicine*. 2018;378(15):1425-1437.
^d Taweh B, Godoy G, Tanaja SS. Focal therapy: a new paradigm for the treatment of prostate cancer. *Reviews in urology*. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC280968/>. Published 2009. Accessed January 7, 2021.



NANOKNIFE PLATFORM



Expanding Indications

Pancreas pivotal study
underway (DIRECT)

Prostate safety study
underway

FDA Pre-Sub meeting
regarding prostate tissue
indication complete



Expanded Reimbursement

Inpatient
ICD-10 Code (2018)
DRGs (2019)

Organ Agnostic
CPT Code (2020)

Outpatient
Outpatient (2021)
ASC (2021)

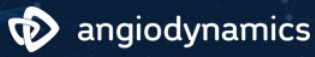


The Team



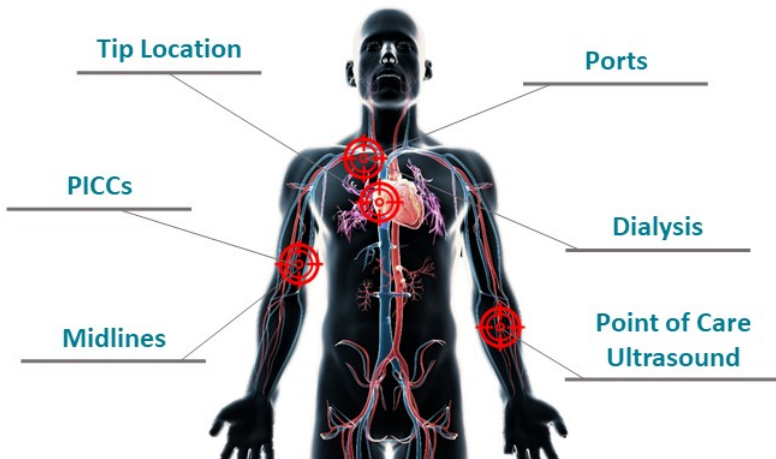
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VASCULAR ACCESS



VASCULAR ACCESS

Safely delivering medication to patients



PORTFOLIO

Delivering on our product road map including development of an integrated navigation & tip location technology that enables the use of our BioFlo PICC.



MARKET ACCESS

Maximize clinical differentiation by reducing thrombus accumulation through the utilization of our BioFlo family of catheters



PERFORMANCE

Maintain a strong culture of execution and collaboration through disciplined sales & marketing plans

First Half FY2021 Highlights

Financial Performance*

\$ in Millions (except per share data)	1H FY2021	1H FY2020	YOY Change
Revenue	\$143.0M	\$136.0M	5.1%
Gross Margin	53.1%	58.6%	(550 bps)
Net Loss	(\$8,536)	(\$4,011)	(\$4,525)
GAAP EPS	(\$0.22)	(\$0.11)	(\$0.11)
Adjusted EPS	\$0.03	\$0.14	(\$0.11)
Adjusted EBITDA	\$9.6	\$13.7	\$4.1

\$ Millions	Q2 FY2021	Q4 FY2020	YOY Change
Cash	\$58.0	\$54.4	\$3.6
Debt	\$40.0	\$40.0	\$-

Growth From Key Products

Key Product Categories	Q1 FY2021	Q2 FY2021	1H FY2021
AngioVac®	46%	24%	34%
NanoKnife® Disposables	(5%)	30%	12%
Auryon*	\$1.1	\$2.1	\$3.2

- Auryon reflects revenue contribution in quarter vs growth rate due to acquisition date in FY20
- The Company anticipates releasing its Q3 earnings around March 30, 2021. The Company is currently in a quiet period.



* Please see Appendix A for reconciliation of GAAP to Non-GAAP.

ANGIODYNAMICS

Strategic Transformation



PURSUIT OF LARGER MARKETS

Active portfolio management enables us to compete in larger, growing markets relying on technology & innovation to produce measurable patient outcomes

FOCUSED RESOURCE DEVELOPMENT

Resource deployment is focused in areas that offer best opportunities for success

PORTFOLIO TRANSFORMATION

Portfolio transformation & strength is driven by R&D, M&A, and Clinical & Regulatory

TOP TALENT

Portfolio combined with talent drives value

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ANGIODYNAMICS

Barclays Global Healthcare Conference

Jim Clemmer, President & CEO
Stephen Trowbridge, EVP & CFO



Appendix A

Reconciliation of GAAP to Non-GAAP Net Income and EPS

	Six months ended	
	Nov 30, 2020	Nov 30, 2019
	(unaudited)	
Net loss	\$ (8,536)	\$ (4,011)
Amortization of intangibles	9,546	8,398
Change in fair value of contingent consideration	(473)	(303)
Acquisition, restructuring and other items, net (1)	2,447	2,921
Write-off of deferred financing fees (2)	—	593
Tax effect of non-GAAP items (3)	(1,803)	(2,273)
Adjusted net income	\$ 1,181	\$ 5,325

	Six months ended	
	Nov 30, 2020	Nov 30, 2019
	(unaudited)	
Diluted loss per share	\$ (0.22)	\$ (0.11)
Amortization of intangibles	0.25	0.22
Change in fair value of contingent consideration	(0.01)	(0.01)
Acquisition, restructuring and other items, net (1)	0.06	0.08
Write-off of deferred financing fees (2)	—	0.02
Tax effect of non-GAAP items (3)	(0.05)	(0.06)
Adjusted diluted earnings per share	\$ 0.03	\$ 0.14
Adjusted diluted sharecount	38,503	38,120

- (1) Includes costs related to merger and acquisition activities, restructurings, and unusual items, including asset impairments and write-offs, certain litigation, and other items.
- (2) Deferred financing fees related to the old credit agreement were written off during the second quarter of fiscal year 2020.
- (3) Adjustment to reflect the income tax provision on a non-GAAP basis has been calculated assuming no valuation allowance on the Company's U.S. deferred tax assets and an effective tax rate of 23% for November 30, 2020 and 2019.



Reconciliation of Net Loss to Adjusted EBITDA

	Six months ended	
	Nov 30, 2020	Nov 30, 2019
	(unaudited)	
Net loss	\$ (8,536)	\$ (4,011)
Income tax benefit	(1,450)	(682)
Interest expense, net	450	506
Depreciation and amortization	12,936	11,033
Change in fair value of contingent consideration	(473)	(303)
Stock based compensation	4,251	4,226
Acquisition, restructuring and other items, net (1)	2,447	2,921
Adjusted EBITDA	\$ 9,625	\$ 13,690

- (1) Includes costs related to merger and acquisition activities, restructurings, and unusual items, including asset impairments and write-offs, certain litigation, and other items.

AngioVac Cannula Indication for Use: The AngioVac Cannula is indicated for use as a venous drainage cannula and for removal of fresh, soft thrombi or emboli during extracorporeal bypass for up to 6 hours. | **Contraindications:** Contraindicated for patients with severe arterial or venous vascular disease, contraindicated for removal of chronic firmly adherent intravascular material (e.g., atherosclerotic plaque, chronic pulmonary embolism) and for use in the right heart or pulmonary arteries during active cardiopulmonary resuscitation. | Refer to Directions for Use and/or User Manual provided with the product for complete Instructions, Warnings, Precautions, Possible Adverse Effects and Contraindications prior to use of the product. | **AngioVac Circuit Indications for Use:** The AngioVac Circuit is indicated for use in procedure requiring extracorporeal circulatory support for period of up to six hours. | **Contraindications:** Refer to the AngioVac Cannula Directions for Use (DFU) for procedure-specific contraindications. Refer to Directions for Use and/or User Manual provided with the product for complete Instructions, Warnings, Precautions, Possible Adverse Effects and Contraindications prior to use of the product. | **CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a physician. | **Auryon System Indications for Use and Important Risk Information:** The AURYON Atherectomy System is indicated for use in the treatment, including atherectomy, of infrainguinal stenoses and occlusions, including in-stent restenosis (ISR). | **Caution:** Federal (USA) law restricts the use of the system by or on the order of a physician. | Refer to Directions for Use and/or User Manual provided with the product for complete Instructions, Warnings, Precautions, Possible Adverse Effects and Contraindications prior to use of the product. | **NanoKnife System Indications For Use and Important Risk Information US:** The NanoKnife System with six outputs is indicated for surgical ablation of soft tissue. | **CE:** The NanoKnife System is a medical device for cell membrane electroporation. Electroporation is a phenomenon that occurs in cell membranes as cells are exposed to an electrical field of sufficiently high intensity. The electric field acts as a physical stimulus, bringing about alterations in cell membranes that result in increased permeability. | **Contraindications:** Ablation procedures using the NanoKnife System are contraindicated in the following cases: • Ablation of lesions in the thoracic area in the presence of implanted cardiac pacemakers or defibrillators • Ablation of lesions in the vicinity of implanted electronic devices or implanted devices with metal parts • Ablation of lesions of the eyes, including the eyelids • Patient history of Epilepsy or Cardiac Arrhythmia • Recent history of Myocardial Infarction | **Potential Adverse Effects:** Adverse effects that may be associated with the use of the NanoKnife System include, but are not limited to, the following: • Arrhythmia • Atrial fibrillation or flutter • Bigeminy • Bradycardia • Heart block or atrioventricular block • Paroxysmal supraventricular tachycardia • Tachycardia • Reflex tachycardia • Ventricular tachycardia • Ventricular fibrillation • Damage to critical anatomical structure (nerve, vessel, and/or duct) • Fistula formation • Hematoma • Hemorrhage • Hemothorax • Infection • Pneumothorax • Reflex Hypertension • Unintended mechanical perforation • Vagal Stimulation, asystole • Venous Thrombosis | Refer to Directions for Use and/or User Manual provided with the product for complete Instructions, Warnings, Precautions, Possible Adverse Effects and Contraindications. Observe all instructions for use prior to use. Failure to do so may result in patient complications. **CAUTION:** Federal Law (USA) restricts this device to sale by or on the order of a physician. | **Uni-Fuse+ Infusion System Indication for Use and Important Risk Information:** Indications for Use: The Uni-Fuse+ Infusion System is intended for the administration of fluids, including thrombolytic agents and contrast media, into the peripheral and pulmonary artery vasculature. **Contraindications:** The Uni-Fuse+ Infusion System is contraindicated for use in the coronary and cerebral vasculature. The Uni-Fuse+ Infusion System is not intended for the infusion of blood or blood products. Refer to the product insert of the therapeutic solution for indications, contraindications, side effects, cautions and warnings. Refer to Directions for Use provided with the product for complete instructions, warnings, precautions, possible adverse effects, and contraindications. **CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a physician.

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