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FOR
TECHNOLOGY TRANSFER AND RESEARCH COMMITTEE

Committee Meeting: 11/9/2016

Board Meeting: 11/10/2016
Austin, Texas

Wallace L. Hall, Jr., Chairman
Ernest Aliseda
Alex M. Cranberg
Brenda Pejovich
Sara Martinez Tucker

1. U. T. System Board of Regents: Discussion and appropriate action regarding Consent Agenda items, if any, assigned for Committee consideration

RECOMMENDATION

No Consent Agenda items are assigned for review by this Committee. The Consent Agenda begins on Page 184.

2. U. T. System: Update on the U. T. Horizon Fund

3. U. T. System: Report on Alafair Biosciences, Inc., a U. T. Horizon Fund portfolio company

REPORT

Ms. Julie Goonewardene, Associate Vice Chancellor for Innovation and Strategic Investment and Managing Director of the U. T. Horizon Fund, will introduce Daniel Peterson, M.D., Chief Executive Officer of Alafair Biosciences, Inc., a U. T. Horizon Fund portfolio company. Dr. Peterson will report on the activities and progress of Alafair Biosciences, Inc. A PowerPoint presentation is set forth on the following pages.

BACKGROUND INFORMATION

The dual-purpose mission of the U. T. Horizon Fund is to 1) help move novel technologies to the marketplace to impact the world, and 2) create a positive financial return. To achieve its dual-purpose mission, the U. T. Horizon Fund invests both (i) in companies utilizing U. T. System innovations, and (ii) in companies in which U. T. System holds an existing equity interest, but which may not necessarily be utilizing U. T. System innovations.

Alafair Biosciences, Inc., is a U. T. Horizon Fund portfolio company that embodies the Fund's dual-purpose mission. Alafair Biosciences is a medical device company developing hydrogel products that reduce the incidence of unwanted postoperative internal scarring, a common problem with most surgeries that costs the U.S. health care system $3.4 billion annually. The research applicable to this company started in 2007 at U. T. Austin, in the lab of Dr. Christine Schmidt. Two graduate students, Drs. Scott Zawko and Sarah Mayes, were critical to this research and are now key employees of the company. Alafair has received numerous grants to fund the commercialization of its hydrogel technology, including grants from the National Science Foundation and an award from the Texas Ignition Fund in 2008, which was a U. T. System proof-of-concept fund. Since founding the company in 2011, Dr. Peterson and his team have significantly benefited from U. T. Austin entrepreneurial and commercialization resources, including the Austin Technology Incubator, Texas Venture Labs, and the McCombs School of Business Master of Science in Technology Commercialization (MSTC) program. Alafair received clearance for its first product, VersaWrap Tendon Protector, from the U.S. Food and Drug Administration in June 2016 and is currently preparing its launch.

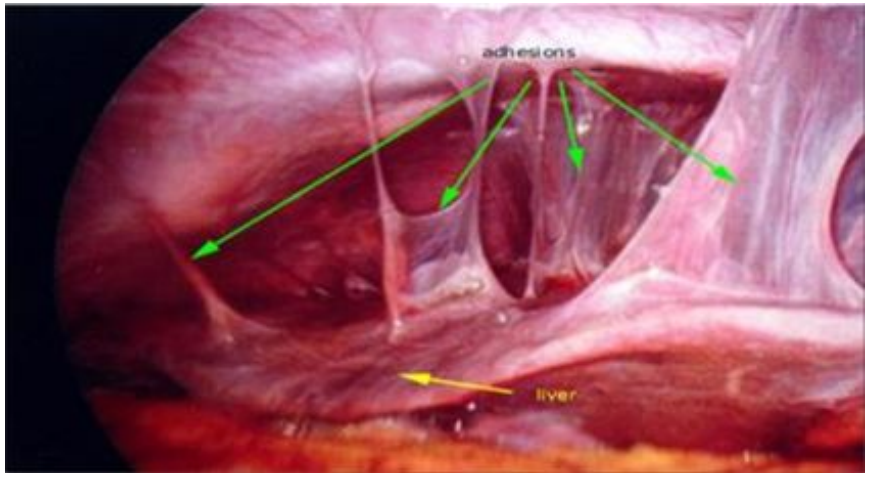
Dr. Peterson is a neurosurgeon and an adjunct professor in biomedical engineering at U. T. Austin. He has over 20 years of experience and leadership in the surgical and health care industries. Dr. Peterson received his M.D. from the University of Colorado Health Science Center School of Medicine and completed both his internship and residency at U. T. Health Science Center - San Antonio.

A Bench to Bedside Success with U. T. Austin Patented Technology

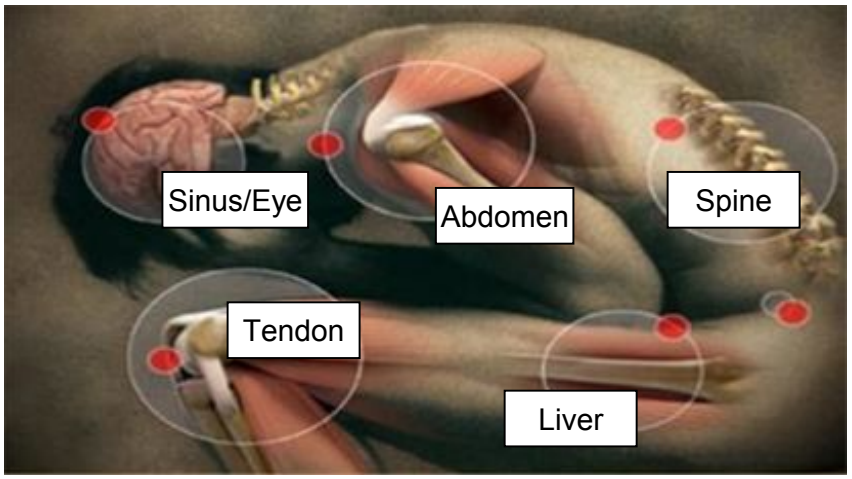
Daniel Peterson, M.D.
CEO, Alafair Biosciences, Inc.

U. T. System Board of Regents' Meeting
Technology Transfer and Research Committee
November 2016

Alafair Biosciences was formed in 2011 to commercialize a U. T. Austin technology that would solve the problem of unwanted postoperative scar tissue formations, known as adhesions



Adhesions occur after any surgical procedure



Adhesions permanently tether tissues that should normally glide against one another

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Adhesions result in a $3.4B annual burden to the U.S. health care system, including hospitalizations and reoperations

The worldwide market for adhesions prevention products is $2.2B, growing at 7% annually

Procedure type	Rate of scar tissue related issues	Procedures in the U.S. (per year)
Tendon	28%	500,000
Abdomen	85%	10,000,000
Ear, Nose, and Throat	36%	350,000
Spine	83%	1,400,000
Eye	42%	1,600,000

Patients suffer

- Tendon contractures
- Bowel obstruction
- Infertility
- Chronic pain
- Blindness
- Immobility
- Reoperation
- Loss of function

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A novel solution was discovered at the U. T. Austin Department of Biomedical Engineering

- Dr. Christine Schmidt previously licensed AVANCE nerve graft to AxoGen
- Detergent treated peripheral cadaver nerve for bridging nerve gaps
- Greater than 30,000 grafts used to date

AxoGen®

- Hydrogel film developed prior to Alafair (2008-2010)
- Lab development supported by Texas Ignition Fund (TIF)
- Hyaluronic acid (HA) and alginate blended hydrogels (2009)

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In February 2011, Alafair Biosciences was formed to license the technology and further develop it into a medical device

- ☑ Working prototype
- ☑ Proof-of-concept results
- ☑ Intellectual property filed
- ☑ Team: clinical perspective, science, entrepreneur
- ☑ Enthusiasm

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In addition to receiving U. T. Horizon Fund (UTHF) investment, Alafair Biosciences has significant U. T. roots

- ☑ U. T. Austin licensed technology
- ☑ Texas Venture Labs Company, 2011
- ☑ Sponsored Research Agreement, 2011-2013
- ☑ Member, Austin Technology Incubator, 2012-present
- ☑ Member lab in Utech Dorm Room, 2013-present
- ☑ TIF proof-of-concept funding
- ☑ Texas Higher Education Fund proof-of-concept funding
- ☑ All employees hold U. T. degrees
- ☑ Preclinical testing done at U. T. Austin
- ☑ Foundational technologies included in the doctoral theses of two U. T. Austin Ph.D. graduates

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The Alafair team is comprised of U. T. Austin alumni

Daniel Peterson, M.D.: Founder, CEO
- Neurosurgeon, Austin Brain and Spine, P.A.
- Adjunct Professor, U. T. Austin

John Joyoprayitno: Founder, COO
- Seasoned entrepreneur with 15 years of experience
- M.S. Technology Commercialization from U. T. Austin

Sarah Mayes, Ph.D.: Founder, Director of Research and Development (R&D)
- Co-inventor of the Alafair Technology
- Ph.D. in biomedical engineering from U. T. Austin

Scott Zawko, Ph.D.: Chief of Science Officer
- Co-inventor of the Alafair Technology
- Ph.D. in chemical engineering from U. T. Austin

Ben Walthall, Ph.D.: Chief Regulatory Officer
- Ph.D. in biochemistry from U. T. Austin
- Former VP of R&D at Zimmer
- Former Director of R&D at Johnson & Johnson

Bhushan Hole, M.S., M.B.A.: VP Product Development
- 10 years of R&D, manufacturing, and marketing experience
- M.B.A. from McCombs School of Business at U. T. Austin

Left to right: Dan Peterson, Scott Zawko, Bhushan Hole, John Joyoprayitno, Sarah Mayes, Ben Walthall, Nancy Beckham

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Non-dilutive funding from bench to technology licensing in 2011

Year	Pre-clinical investigator	Funding entity	Amount	Title
2008	Christine Schmidt	National Science Foundation (NSF)	$655,000	Crystal-templated hydrogels
2008	Christine Schmidt	Texas Higher Education Coordinating Board	$150,000	In-situ crystallization of hydrogels
2008	Christine Schmidt	Texas Ignition Fund (TIF)	$50,000	Engineered hyaluronic acid scaffolds

Non-dilutive funding after technology licensing to Alafair Biosciences in 2011

Year	Pre-clinical investigator	Funding entity	Amount	Title
2011	Daniel Peterson	University Medical Center-Brackenridge	$45,000	Proof of concept (POC) animal model
2012	Daniel Peterson	National Institutes of Health (NIH)	$508,000	Adhesion prevention development

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Dilutive funding requirements to take the technology from a U. T. Austin lab to an FDA-cleared medical device

Date	Type	Share Price	Amount of raise
July 2011	Series AA (Angel investors)	$1.40000	$886,400
August 2012	Series AA-1 (Angel investors)	$1.77295	$525,001
July 2016	Series A (Angels and institutions)	$3.08979	$1,999,993[1]
July 2016	Texas Emerging Technology Fund (TETF) convertible debt financing	$3.08979	$2,262,919

1. UTHF invested $400,000 in Series A, July 2016

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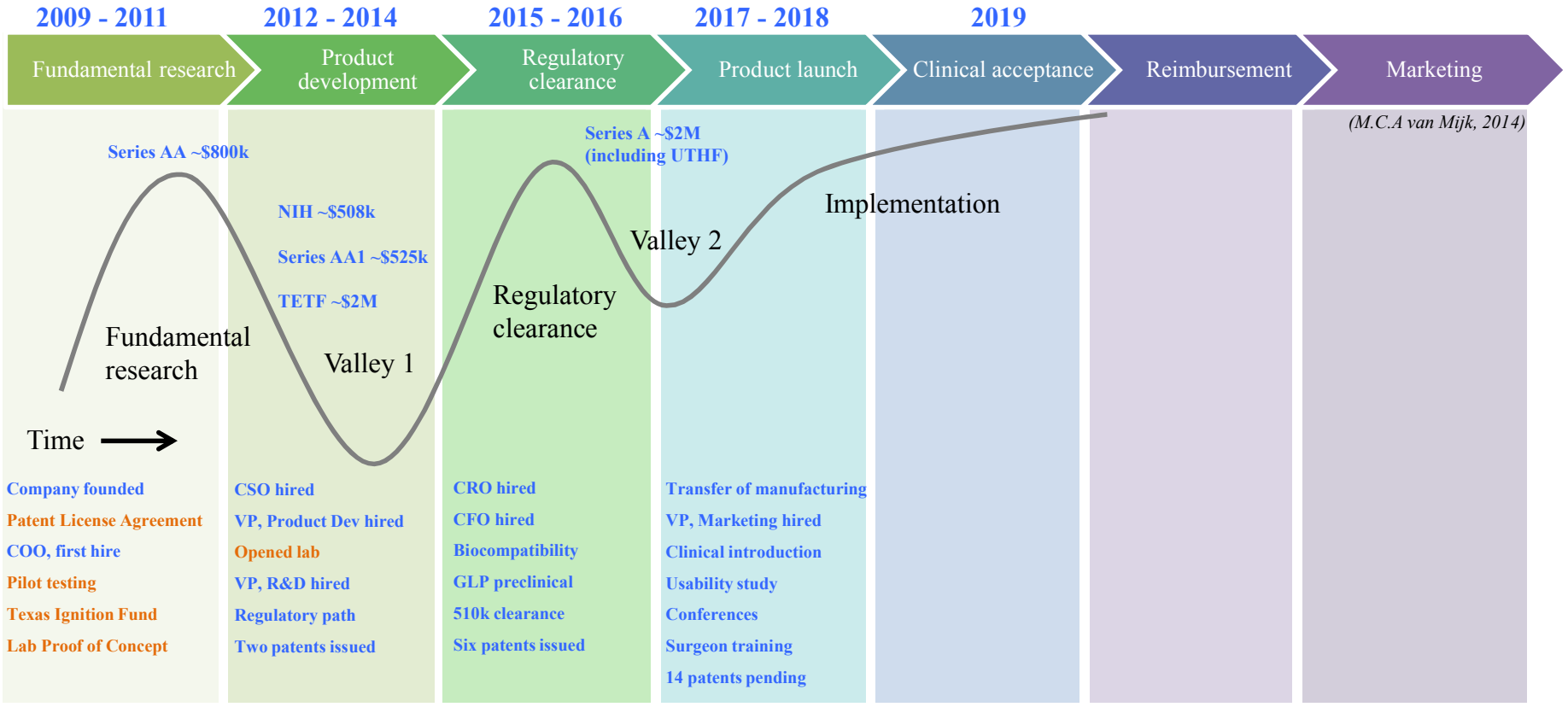
The history of Alafair: A 10-year project



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Milestones

Event	Timeframe	Dilutive funds	Non-dilutive funds	Valuation
Founded	Feb. 2011			$2.8M
License agreement established	Mar. 2011			
Hired COO	Mar. 2011			
Series AA Financing	Feb. 2012	$875k		$3.675M
Hired CSO	Jun. 2012			
STTR NIH Phase I Awarded	Sept. 2012		$100k	
Hired VP Product Development and Marketing	Sept. 2012			
Opened lab	May 2013			
Hired VP R&D	Jun. 2013			
Series AA-1 Financing	Aug. 2013	$525k		$6.025M
STTR NIH Phase II Awarded	Sept. 2013		$408k	
TETF Tranche 1	Feb. 2014	$1M		
First patent issued (US 8,668,863)	Mar. 2014			
Second patent issued (US 8,728,499)	May 2014			
TETF Tranche 2	Nov. 2014	$500k		
Third patent issued (US 8,946,194)	Feb. 2015			
TETF Tranche 3	Mar. 2015	$500k		
Hired CRO	Jun. 2015			
Fourth patent issued (US 9,095,558)	Aug. 2015			$10.5
First 510k submission	Feb. 2016			
Fifth patent issued (US 9,320,827)	Apr. 2016			
Received first 510k clearance	Jun. 2016			
Sixth patent issued (AU 2013359344)	Jul. 2016			
Series A Financing	Jul. 2016	$2M (including UTHF)		$14.75M

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Alafair technology provides ultrathin, sutureless, animal-free tissue protection from unwanted postsurgical scarring

1 Ultrathin, translucent, repositionable membrane protects injured tissues

2 Touchless, aqueous solution relaxes membrane onto delicate surfaces and geometries

Sutureless delivery

3 Strong tissue adherence and high conformability

Bioresorbable protective layer is animal product free

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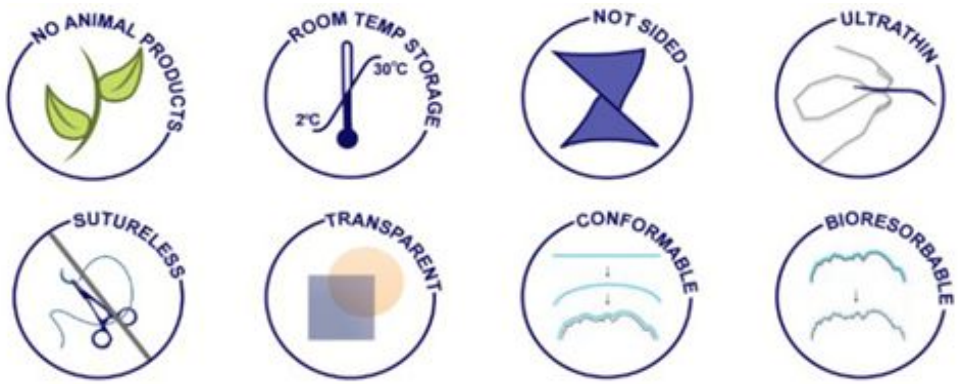
Alafair technology offers unique advantages



Key Features		
• Low-cost raw materials	• Translucent	• Repositionable
• Low-cost manufacturing	• Implanted wet or dry	• Compatible with minimally invasive techniques
• No special storage conditions	• Implanted in any orientation	• Highly conformable
• Biocompatible (ISO 10993)	• Ultrathin profile for placement between confined tissues	• Sutureless delivery
• Bioresorbable	• Easily cut to size	• Non-swelling / non-constricting
• No animal products or by-products		

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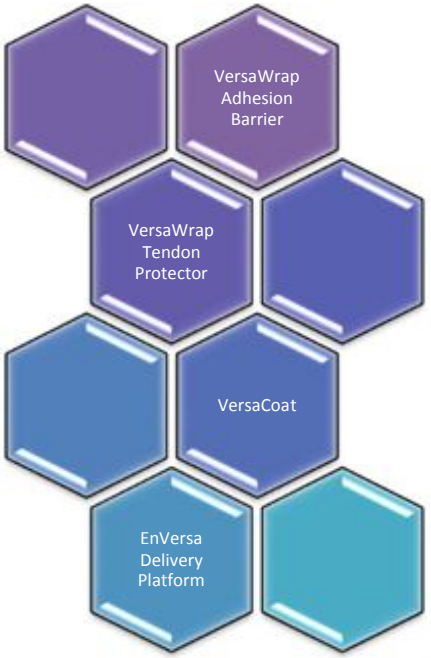
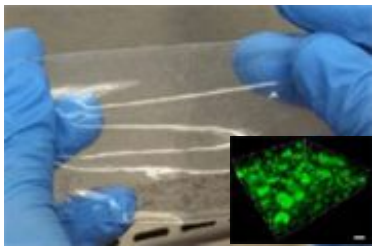
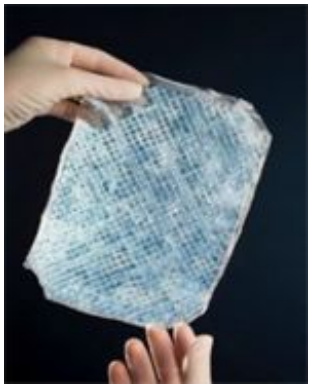
The Alafair technology presents a versatile platform to protect tissue, to protect devices, and to optimize delivery of powders or small molecules







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Alafair technology licensed from U. T. is protected by a robust IP portfolio

	Patent Number	Status	Title
Issued Patents	US 8,668,863	Issued 3/11/2014	Dendritic macroporous hydrogels prepared by crystal templating
	US 8,728,499	Issued 5/20/2014	Dendritic macroporous hydrogels prepared by crystal templating (continuation)
	US 9,320,827	Issued 4/26/2016	Dendritic macroporous hydrogels prepared by crystal templating (continuation)
	US 8,946,194	Issued 2/03/2015	One-step processing of hydrogels for mechanically robust and chemically desired features
	US 9,095,558	Issued 8/04/2015	Anti-adhesive barrier membrane using alginate and hyaluronic acid for biomedical applications
	AU 2013359344	Issued 7/14/2016	Hydrogel membrane for adhesion prevention
Patent Applications	US 14/758,873	Filed 12/11/2013	Hydrogel membrane for adhesion prevention
	US 14/604,298	Filed 1/23/2015	One-step processing of hydrogels for mechanically robust and chemically desired features (continuation)
	US 14/803,258	Filed 7/20/2015	Anti-adhesive barrier membrane using alginate and hyaluronic acid for biomedical applications (continuation)
	US 15/135,978	Filed 4/22/2016	Dendritic macroporous hydrogels prepared by crystal templating (continuation)
	PCT/US2011/55469	Nationalized in EU and JP	Anti-adhesive barrier membrane using alginate and hyaluronic acid for biomedical applications
	PCT/US2013/74388	Nationalized in BR, CA, CN, EU, IN, JP, KR, MX	Hydrogel membrane for adhesion prevention