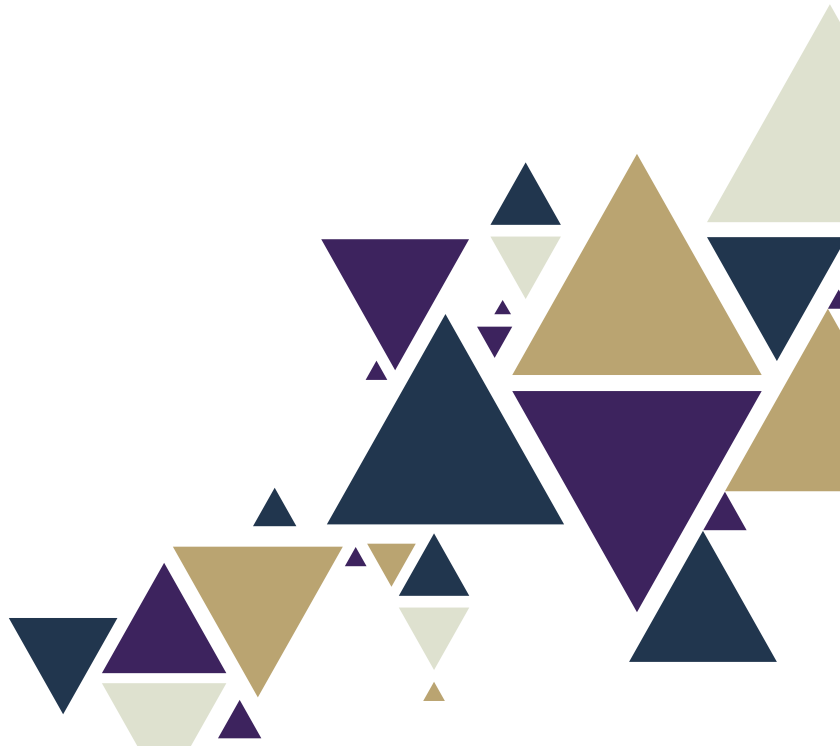
Nonconfidential Deck

aero therapeutics

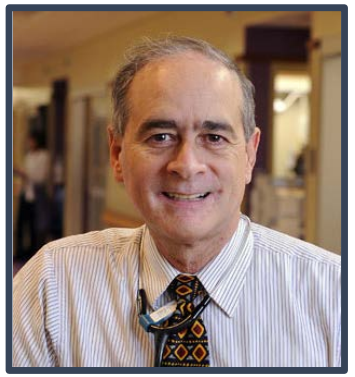
Anjelica Gonzalez PhD
Co-founder & Inventor

Innovation Summit 19May2021

Every breath matters.



Aero Therapeutics, Inc
Core Team, Board and CRO Partner



Dr. Anjelica Gonzalez	**Mr. Jamison Langguth**	**Dr. Wally Carlo**	**Dr. Brian Harvey**	**Confidential**
Inventor & Co-founder	CEO & Co-founder	Board - Clinical	Board - Regulatory	CRO – Product Dev
PHD	MPH, MSED, ‘20 Yale Blavatnik Fellow	MD	MD, PHD	MS
Biomedical Engineer & Yale Faculty	10 Years Clinops, 2 Years Biotech BD	Neonatologist & Pediatrician	Ex-FDA & Pfizer, Yale Entrepreneur in Residence	Fixed fee services from design to full scale manufacturing

Neonatal Respiratory Distress

All Settings:
Full Range of Potential Devices

Improvised Device

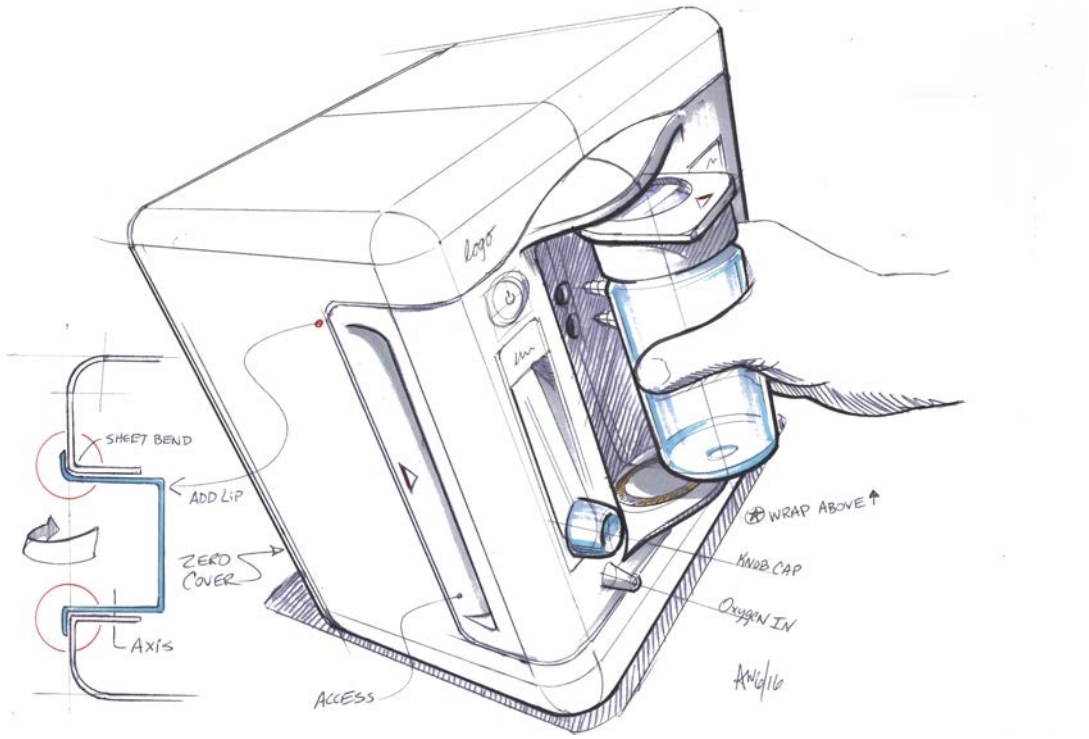
Full Mechanical Ventilator

CPAP

Our Device

High Flow

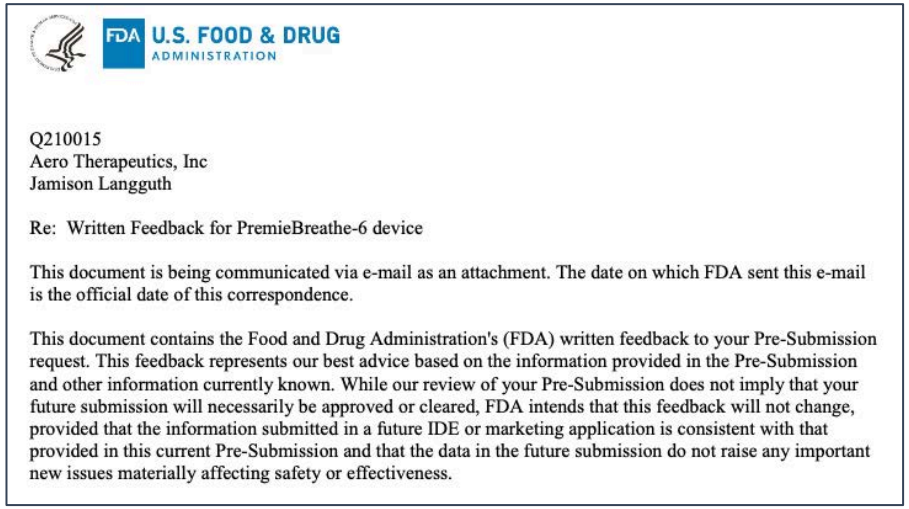
PremieBreathe Respirator



Intellectual Property:
PORTABLE AND COMPACT SYSTEM FOR DELIVERY OF HUMIDIFIED HIGH FLOW NASAL CANNULA (HHFNC) THERAPY IN NEONATES AND INFANTS" Docket Number PCT Filed 23Aug2019: 047162-5227-P3US

Company Update Jan - May 2021

- **JLABs San Diego residency** began in January.
- **We met with FDA** in March about our proposed pathway and received an explicit roadmap towards approval in the US.
- We have a **clear pathway to a commercial product in the US.**



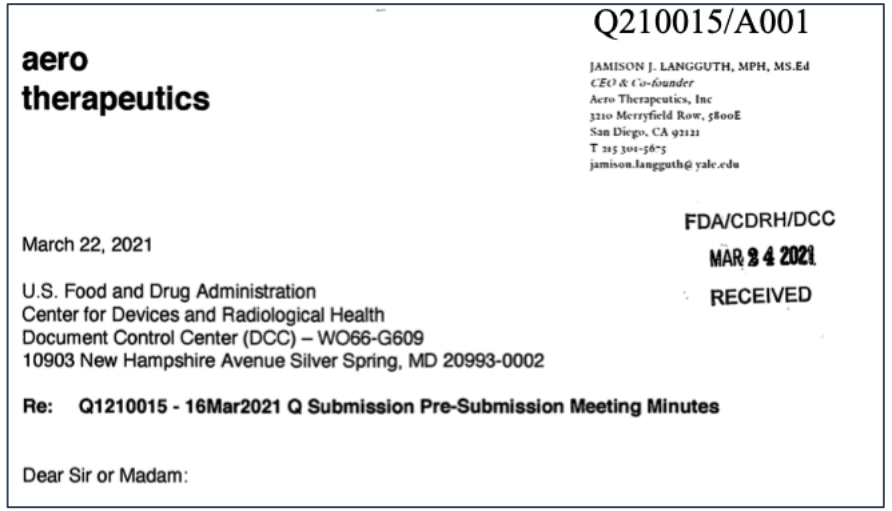
FDA U.S. FOOD & DRUG ADMINISTRATION

Q210015
Aero Therapeutics, Inc
Jamison Langguth

Re: Written Feedback for PremieBreathe-6 device

This document is being communicated via e-mail as an attachment. The date on which FDA sent this e-mail is the official date of this correspondence.

This document contains the Food and Drug Administration's (FDA) written feedback to your Pre-Submission request. This feedback represents our best advice based on the information provided in the Pre-Submission and other information currently known. While our review of your Pre-Submission does not imply that your future submission will necessarily be approved or cleared, FDA intends that this feedback will not change, provided that the information submitted in a future IDE or marketing application is consistent with that provided in this current Pre-Submission and that the data in the future submission do not raise any important new issues materially affecting safety or effectiveness.



Q210015/A001

aero
therapeutics

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FDA/CDRH/DCC
MAR 24 2021
RECEIVED

March 22, 2021

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center (DCC) – WO66-G609
10903 New Hampshire Avenue Silver Spring, MD 20993-0002

Re: Q1210015 - 16Mar2021 Q Submission Pre-Submission Meeting Minutes

Dear Sir or Madam:

Focused US Competition

Vapotherm®
HiVNI® TECHNOLOGY
100 Domain Drive, Exeter, NH 03833
855.690.6086 | www.vapotherm.com

Quote Number	00020431
Created Date	11/9/2020
Expiration Date	12/9/2020
Shipping Terms	FOB Origin
Payment Terms	Net 30
Prepared For	Yale-New Haven Hospital
Prepared By	Michael Calderoni
Email	mcalderoni@vtherm.com

Product	Product Description	Quantity	Unit Price	Total Price
PF-PLUS-US	Vapotherm Precision Flow Plus Excludes Vapotherm Roll Stand	1.00	USD 8,667.00	USD 8,667.00
		Grand Total		USD 8,667.00

VapoCare Service Program available on Precision Flow Units: one set fee that covers service and preventive maintenance . Please ask your Area Manager for pricing

	Incumbent to beat	**PremieBreathe**
	Vapotherm HVNI	
Humidified	✓	✓
Warmed	✓	✓
Mixed O2	✓	✓
Price (USD)	**~$8,667**	**$1K – $3K**
Estimated COGS	**$4,000 – $6,000**	**$300 – $1,000**

Key Revenue Channels

Compete on price

We can build these devices cheaper and still sell for a profitable margin.

Consumables

We are exploring: nasal cannulas, UV, wicking, filters, & heavy metals.

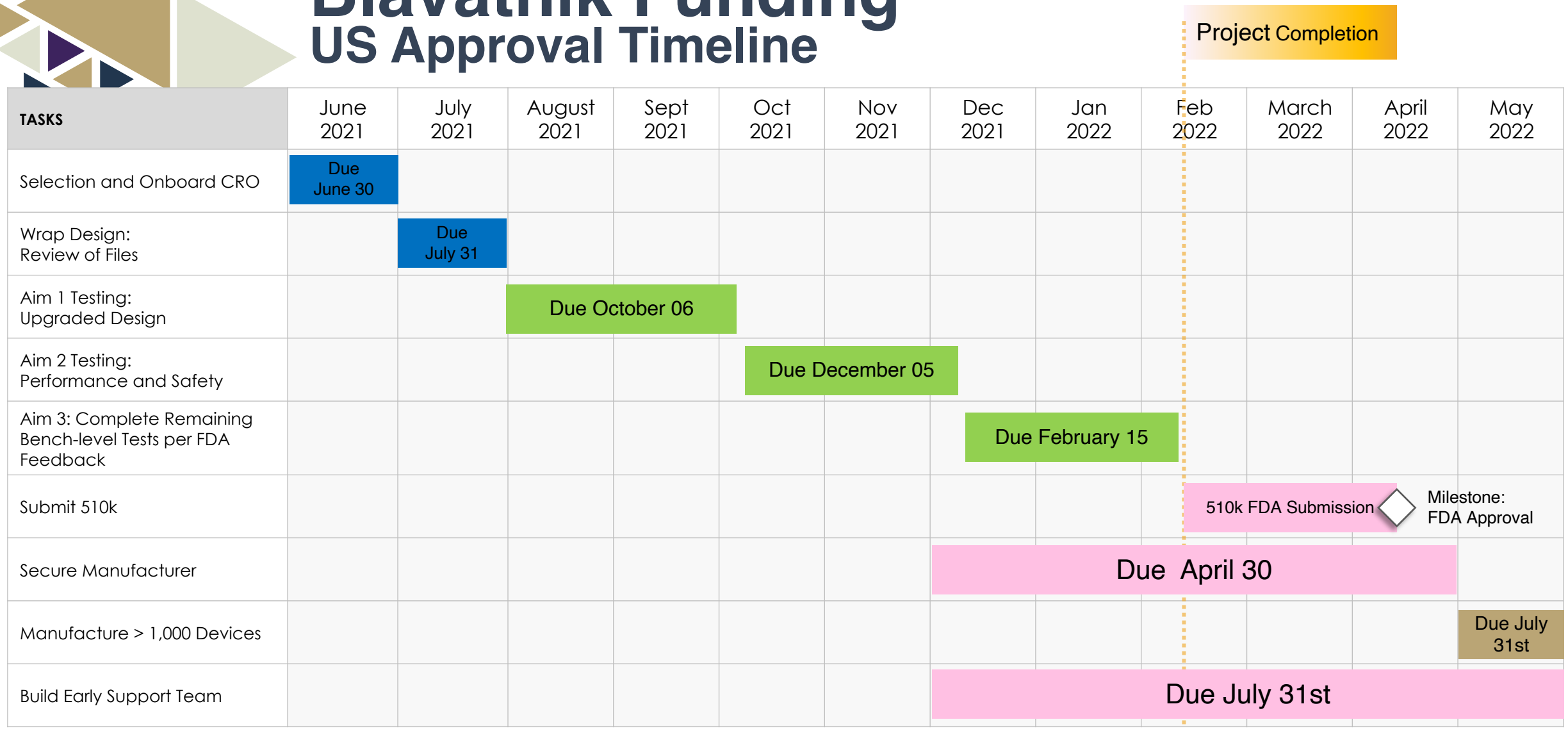
Bundling opportunities

There have been great strides in O2 concentrators but O2 mixers have not innovated for these to flourish.

Risk sharing potential

Down the road we could offer the hardware cheaper than competitors and capture some of the outcomes value.

Blavatnik Funding
US Approval Timeline



Accelerators, Awards, Funding & Partners

Raised $280,000 as of 05 May 2021

Johnson & Johnson

USAID

newchip

INNOVATION | JLABS

VENTUREWELL™
idea to impact

SAVING LIVES AT BIRTH:
A GRAND CHALLENGE FOR DEVELOPMENT

Sustainable Health Initiative

Yale Institute for Global Health

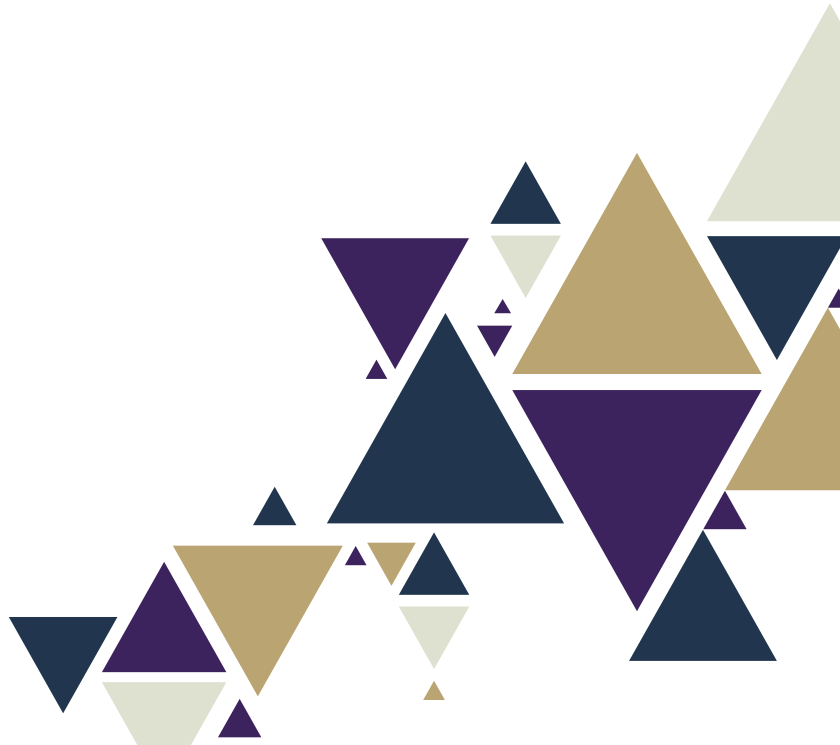
HARVARD | BUSINESS | SCHOOL

Association of Northern California Alumni Angels

HBS ALUMNI NEW VENTURE COMPETITION

Exit – Acquisition

www.breatheaero.com



Pre-Pandemic Market Data

Nasal Cannula High Flow Delivery Market Size

USD **9.8** BN By 2025

N=3, SD=1,167M

Global CAGR

~10.5%

N=5, SD=1.6%

There is a sizable market for this kind of technology that is growing.

Inpatient & Outpatient Reimbursement Strategy

Unlisted Pulm CPT Code 94662:	$136.32
CPAP designated CPT Code 94660:	$186.38
E&M APC Code 5041:	$734

- Encourage hospitals to use on an unlisted pulmonary service bundled into the Critical Care Evaluation & Management (E&M) CPT code for a higher reimbursement.
- This mirrors a CPAP strategy, where the use of a CPAP is bundled in the same APC.

Post-Approval Timeline

ENTRY

TASKS	April 2022	May 2022	June 2022	July 2022	August 2022	Sept 2022	Oct 2022	Nov 2022	Dec 2022	Jan 2023	Feb 2023	March 2023
Submit 510k	FDA Approval											
Build Clinical Data Team	Due June 30th											
Seek IRB approvals for clinical data collection at H & Y	Due July 31st											
Clinical Data Collection					Data Collection Due Jan 31st						Publication Submission	
Publication Goal											Due March 31st	
Ongoing Sales Efforts					Ongoing							

Clinical Partnerships

Anjelica Gonzalez

Aero Project Management Team