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

June 29, 2017
Date of Report (Date of earliest event reported)

Windtree Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**000-26422**	**94-3171943**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification Number)

2600 Kelly Road, Suite 100
Warrington, Pennsylvania 18976
(Address of principal executive offices)
(215) 488-9300
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

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))

Item 8.01. Other Events.

On Thursday, June 29, 2017, Windtree Therapeutics, Inc. (the "Company") issued a press release and hosted a conference call and live webcast to announce top line results for its AEROSURF® phase 2b clinical trial evaluating aerosolized KL_4 surfactant for the treatment of respiratory distress syndrome (RDS) in premature infants, 28 to 32 week gestational age, receiving nasal continuous positive airway pressure (nCPAP) for RDS. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference. A copy of the presentation materials is attached as Exhibit 99.2 to this Current Report on Form 8-K and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release dated June 29, 2017

99.1 Presentation materials dated June 29, 2017

Cautionary Note Regarding Forward-looking Statements:

To the extent that statements in the press release, presentation materials and this Current Report on Form 8-K are not strictly historical, including statements about the Company's clinical development programs, including AEROSURF®, business strategy, outlook, objectives, plans, intentions, goals, future financial conditions, future collaboration agreements, the success of the Company's product development activities, or otherwise as to future events, such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All such forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from the statements made. Such

risks and others are further described in the Company's filings with the Securities and Exchange Commission including the most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto.

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.

Windtree Therapeutics, Inc.

By: /s/ Craig Fraser
Craig Fraser
President and Chief Executive Officer

Date: June 29, 2017

Exhibit 99.1

Windtree Announces Top-Line Results from AEROSURF® Phase 2b Clinical Trial for the Treatment of Respiratory Distress Syndrome (RDS) in Premature Infants

-Company to Hold Conference Call Today at 4:30 p.m. EDT-

WARRINGTON, PA – June 29, 2017 – Windtree Therapeutics, Inc. (OTCQB: WINT), a biotechnology company focused on developing aerosolized KL4 surfactant therapies for respiratory diseases, today announced top line results for its AEROSURF® phase 2b clinical trial evaluating aerosolized KL4 surfactant for the treatment of respiratory distress syndrome (RDS) in premature infants, 28 to 32 week gestational age, receiving nasal continuous positive airway pressure (nCPAP) for RDS. A total of 221 patients were enrolled at 48 sites in North America, Europe and Latin America.

The AEROSURF phase 2b clinical trial was a multicenter, randomized, controlled study with masked treatment assignment in premature infants receiving nCPAP for RDS, and was designed to evaluate aerosolized KL4 surfactant administered to premature infants 28 to 32 week gestational age in two dose groups (25 and 50 minutes), with up to two potential repeat doses, compared to infants receiving nCPAP alone. The key objectives of this trial were to:

- evaluate efficacy by assessing: (i) incidence of nCPAP failure (defined as the need for intubation), (ii) time to nCPAP failure, and (iii) physiological parameters indicating the effectiveness of lung function;
- define the dose regimen(s) for the planned phase 3 clinical program;
- provide an estimation of the expected efficacy margin of AEROSURF treatment;
- evaluate performance and further the development of the aerosol delivery system (ADS); and
- further characterize the AEROSURF safety profile

Based on the planned top-line results, data show that AEROSURF did not meet the primary endpoint of a reduction in nCPAP failure at 72 hours. The nCPAP failure rates for the 25 minute (n=71) and 50 minute (n=72) dose groups were comparable to nCPAP alone (n=71) (44 percent, 44 percent and 44 percent, respectively).

The lack of a desired top-line treatment effect was due in large part to an unexpected rate of treatment interruptions. These treatment interruptions were primarily due to specific lots of disposable cartridge filters with a higher tendency to clog and occurred in about 23% of active enrollments, predominantly in the longer 50 minute dose group.

Analysis of data of patients in the 50 minute dose group whose dose was not impacted by device-related treatment interruptions (n=45) resulted in a nCPAP failure rate of 31 percent compared to 44 percent in the control group which is a 13 percent absolute reduction or a 30 percent relative reduction in nCPAP failure compared to control. These data suggest a meaningful treatment effect in line with our targeted outcome.

For AEROSURF patients who experienced nCPAP failure requiring intubation and mechanical ventilation, the time on mechanical ventilation and supplemental oxygen, as well as the level of required oxygen support, appeared to be lower compared to control patients who experienced nCPAP failure. These parameters are important risk factors for bronchopulmonary dysplasia, a chronic lung disease of the newborn and important determinants of duration of intensive care and costs of treating RDS.

Overall, the safety and tolerability profile of the AEROSURF treated patients was generally comparable to the control group. All reported adverse events and serious adverse events were those that are common and expected among this fragile patient population. The incidence of adverse events and serious adverse events in the AEROSURF and control groups were generally comparable and there was no pattern observed of increasing adverse events or serious adverse events with increasing doses of AEROSURF. Furthermore, the safety and tolerability profile of the AEROSURF treated patients both with and without treatment interruptions was generally comparable to the control group.

“While the results did not meet the planned top-line analysis, we are very encouraged to see that, when dose is delivered as intended, the 50 minute dose exhibited a positive treatment effect with a safety profile comparable to that of nCPAP and consistent with the results we obtained in our previously completed phase 2a open-label clinical trial in similar gestational age infants,” said Steve Simonson, Chief Medical Officer.

Based on the results of this study, the Company plans to work with regulators and develop a phase 3 regulatory and clinical plan using its next generation ADS, the design of which has been demonstrated to mitigate the device-related treatment interruptions experienced in this phase 2b clinical trial.

“While analysis of data is ongoing, we believe we have achieved a number of important clinical objectives including providing evidence of a treatment effect in the higher dose and the potential to replicate desired results. We look forward to finalizing a regulatory and clinical plan to incorporate our next generation ADS, along with other learning's from this trial, as we pursue a path that will allow us to advance AEROSURF into phase 3 development,” commented Craig Fraser, Chief Executive Officer.

This clinical trial was supported, in part, by a $1.9 million Phase II award of a $2.4 million Fast Track Small Business Innovation Research (SBIR) grant from the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH) under award number 4R44HL107000-02. The content of this press release is solely the responsibility of the Company and does not necessarily represent the official views of the National Institutes of Health.

Conference Call and Webcast Details
The Company will host a conference call and webcast (including a slide presentation) today at 4:30 p.m. EDT to review and discuss the results of the AEROSURF phase 2b clinical trial.

The live webcast, including a slide presentation, can be accessed at http://windtreetx.investorroom.com/events . To participate in the live call and take part in the question and answer session, dial (844) 802-2436 (domestic) or (412) 317-5129 (international).

A replay of the conference call will be accessible one hour after completion through July 6, 2017 by dialing (877) 344-7529 (domestic) or (412) 317-0088 (international) and referencing conference number 10110052. An archive of the webcast will be available on the Company’s website at http://windtreetx.investorroom.com/events.

About Windtree Therapeutics
Windtree Therapeutics, Inc. is a clinical-stage biotechnology company focused on developing novel surfactant therapies for respiratory diseases and other potential applications. Windtree's proprietary technology platform includes a synthetic, peptide-containing surfactant (KL4 surfactant) that is structurally similar to endogenous pulmonary surfactant and novel drug-delivery technologies being developed to enable noninvasive administration of aerosolized KL4 surfactant. Windtree is focused initially on improving the management of respiratory distress syndrome (RDS) in premature infants and believes that its proprietary technology may make it possible, over time, to develop a pipeline of KL4 surfactant product candidates to address a variety of respiratory diseases for which there are few or no approved therapies.

For more information, please visit the Company's website at www.windtreetx.com.

Forward-Looking Statements
To the extent that statements in this press release are not strictly historical, all such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from the statements made. Examples of such risks and uncertainties include: the risk that, as a development company, with limited resources and no operating revenues, the Company’s ability to continue as a going concern in the near term is highly dependent upon whether the results of the AEROSURF phase 2b clinical trial are sufficient to support a strategic or financing transaction and potential pathway for phase 3 development; risks that Windtree will be unable to secure significant additional capital as and when needed, or to access debt or equity financings when needed, if at all; risks related to the transfer of the Company’s common stock to the OTCQB® market; risks related to Windtree's AEROSURF development program and other aerosolized KL4 surfactant development programs in the future, which may involve time-consuming and expensive preclinical and clinical trials and which may be subject to potentially significant delays or regulatory holds, or fail; risks related to the development of aerosol delivery systems (ADS) and related components; risks related to technology transfers to contract manufacturers and problems or delays encountered by Windtree, contract manufacturers or suppliers in manufacturing drug products, drug substances, ADS on a timely basis and in sufficient amounts; risks relating to rigorous regulatory requirements, including those of (i) the FDA or other regulatory authorities that may require significant additional activities, or may not accept or may withhold or delay consideration of applications, or may not approve or may limit approval of Windtree's products and (ii) changes in the national or international political and regulatory environment, which may make it more difficult to gain regulatory approvals; and other risks and uncertainties described in Windtree's filings with the Securities and Exchange Commission including the most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto.

Contact Information:
John Tattory
Senior Vice President and Chief Financial Officer
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WINDTREE THERAPEUTICS™

Investor Conference Call
AEROSURF® Phase 2b Update
June 29, 2017

OTCQB:WINT

Forward-looking Statement

To the extent that statements in this presentation are not strictly historical, including statements about the Company's clinical development programs, business strategy, outlook, objectives, plans, intentions, goals, future financial conditions, future collaboration agreements, the success of the Company's product development activities, or otherwise as to future events, such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The forward-looking statements contained in this presentation are subject to certain risks and uncertainties that could cause actual results to differ materially from the statements made. These risks are further described in the Company's periodic filings with the Securities and Exchange Commission (SEC), including the most recent reports on Forms 10-K, 8-K and 10-Q, and any amendments thereto ("Company Filings")

Under no circumstances shall this presentation be construed as an offer to sell or as a solicitation of an offer to buy any of the Company's securities. In addition, the information presented in this deck is qualified in its entirety by the Company Filings. The reader should refer to the Company Filings for a fuller discussion of the matters presented here.

AEROSURF® Phase 2 Program Components

Study / Activity	Rationale / Objective	Status
Phase 2a	Initial safety & tolerability (29-34 wk gestational age (GA))	Completed
2a Expansion	Extending the dose range in 29-34 wk GA	Completed
Phase 2a	Safety and tolerability in 26-28 wk GA	Completed
Phase 2b	28 – 32 wk GA - Dose and evidence of clinical effect	Completed
Other Studies:		
Observational Study	Understand treatments and outcomes for our target population	>2000 pts data collection complete
Lung Deposition Study	Assess inhaled surfactant distribution in non-human primate lungs	Data presented
Other Activities:		
Device Development	Design verification, validation and clinical experience with next generation, phase 3 and commercial device	On Track for 2H 2017
FDA Interaction	Confirm strategic direction and operational approach	Successful April '16 Meeting and subsequent Fast Track Designation

AEROSURF® Phase 2b
in Premature Infants 28-32 Week GA

AEROSURF® Phase 2b Study (28 to 32 wk GA)

Trial Objectives

- Evaluate safety and tolerability
- Demonstrate efficacy
- Determine effect size for phase 3 planning
- Dose(s) selection for phase 3 (or additional phase 2 confirmation)
- Evaluate performance of our phase 2 prototype device

AEROSURF® Phase 2b Study (28 to 32 wk GA)

Trial Design

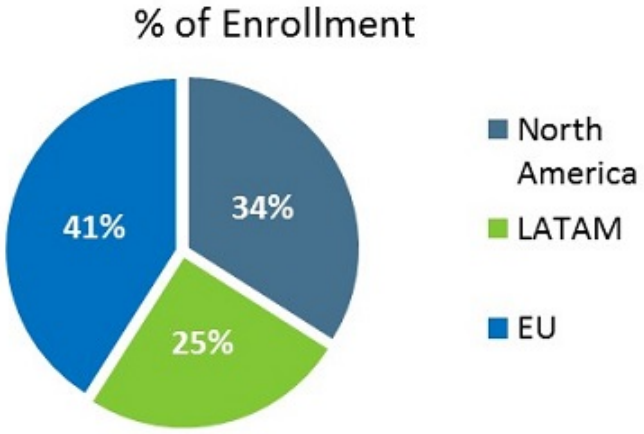
- 3 dose groups:
  - ✓25 minute (40 mg/kg) (with up to 2 repeat doses)
  - ✓50 minute doses (80 mg/kg) (with up to 2 repeat doses)
  - ✓Control (nCPAP alone)
- Primary endpoint: nCPAP failure (defined as the need for intubation and delayed surfactant)
- Up to 240 patients (up to 80 per group) total
- Treatment assignment was blinded
- Studied in premature infants 28 to 32 wk GA with RDS
  - 28 week GA added Dec 2016 after internal evaluation and independent Steering Committee consultation

AEROSURF® Phase 2b Study (28 to 32 wk GA)

221 Patients Enrolled

50 sites participated:

• US	19
• Canada	4
• Poland	8
• Netherlands	1
• Hungary	6
• Ireland	2
• Chile	7
• Colombia	3



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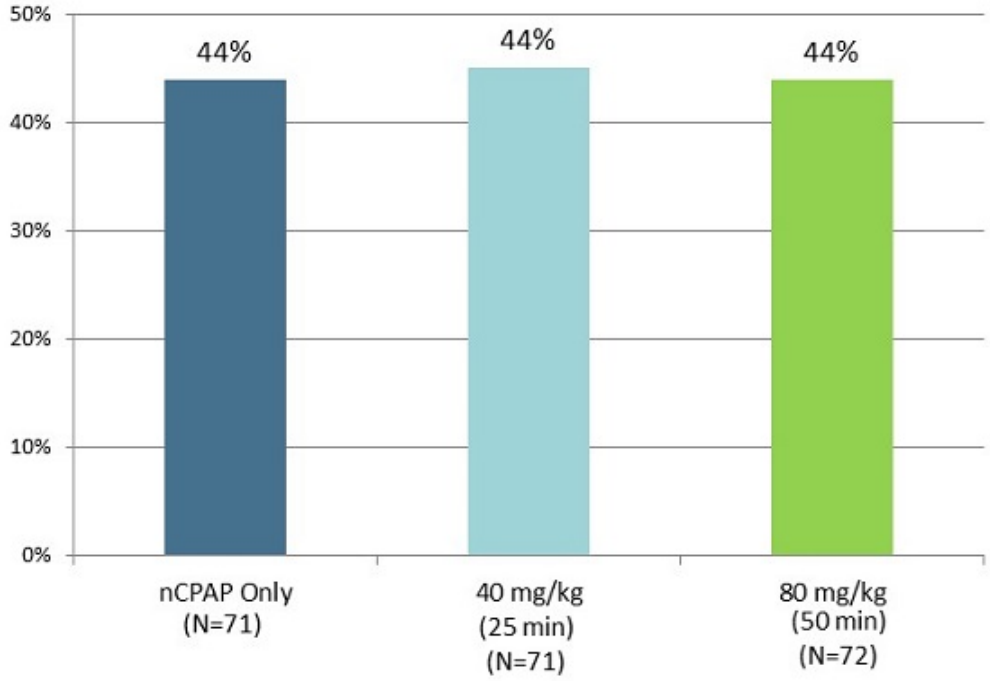
AEROSURF® Phase 2b Clinical Highlights

- The planned top line analysis of the primary endpoint did not show a treatment effect
- Excluding the impact of treatment interruptions, the 50 minute dose achieved a positive treatment effect on the upside of our target and replicates the results in our 2a study (executed in the U.S. in similar gestational age infants)
- The safety profile remains similar to control (nCPAP alone)
- Additional Learnings:
  - Time and consistency of dosing are important factors when delivering aerosolized surfactants. Faster time to treatment and more timely repeat dosing may enhance treatment effect
  - For AEROSURF patients who experienced nCPAP failure, the time on mechanical ventilation and supplemental oxygen as well as level of required oxygen support appear to be lower compared to control patients who experienced nCPAP failure

Incidence of nCPAP Failure at 72 Hours

mITT, All Patients receiving Study Treatment



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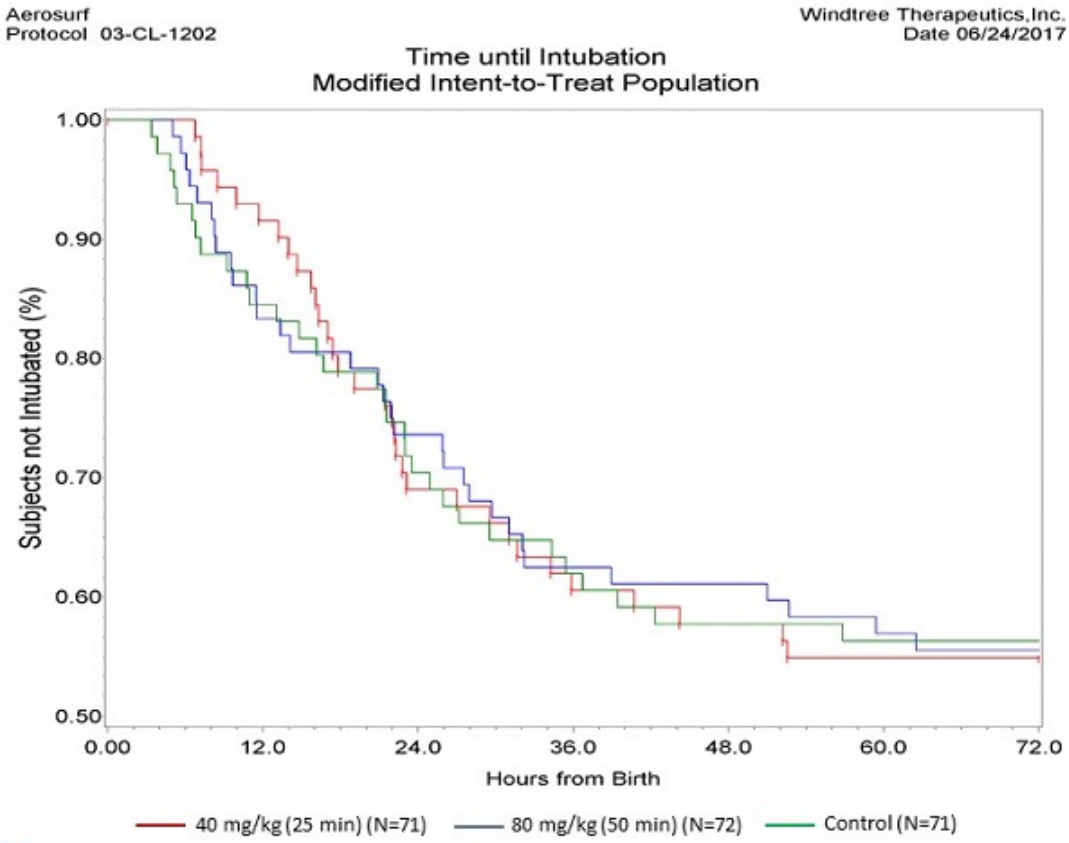
Time to nCPAP Failure (from birth)

mITT, All Patients receiving Study Treatment



Treatment Interruption Overview

- Treatment interruptions occur after aerosol delivery begins and is then stopped prior to completion of the specified time/dose
- Phase 2a Study - Open Label (80 patients)
  - Only ~5% of doses were interrupted and did not impact results
- Phase 2b - Blinded study (221 patients)
  - We found treatment interruptions were primarily due to disposable cartridge filters with a higher tendency to clog and these occurred in about 23% of active enrollments
  - Occurred more often in the longer 50 minute dose group
  - Occurred more often earlier in the study and in limited lots in specific geographies

Disposable aerosol generator cartridges

- KL4 surfactant loaded into syringe/syringe pump.
- KL4 surfactant pumped under high pressure to deliver to heated capillary with very small orifice.
- Small filter between syringe and capillary.

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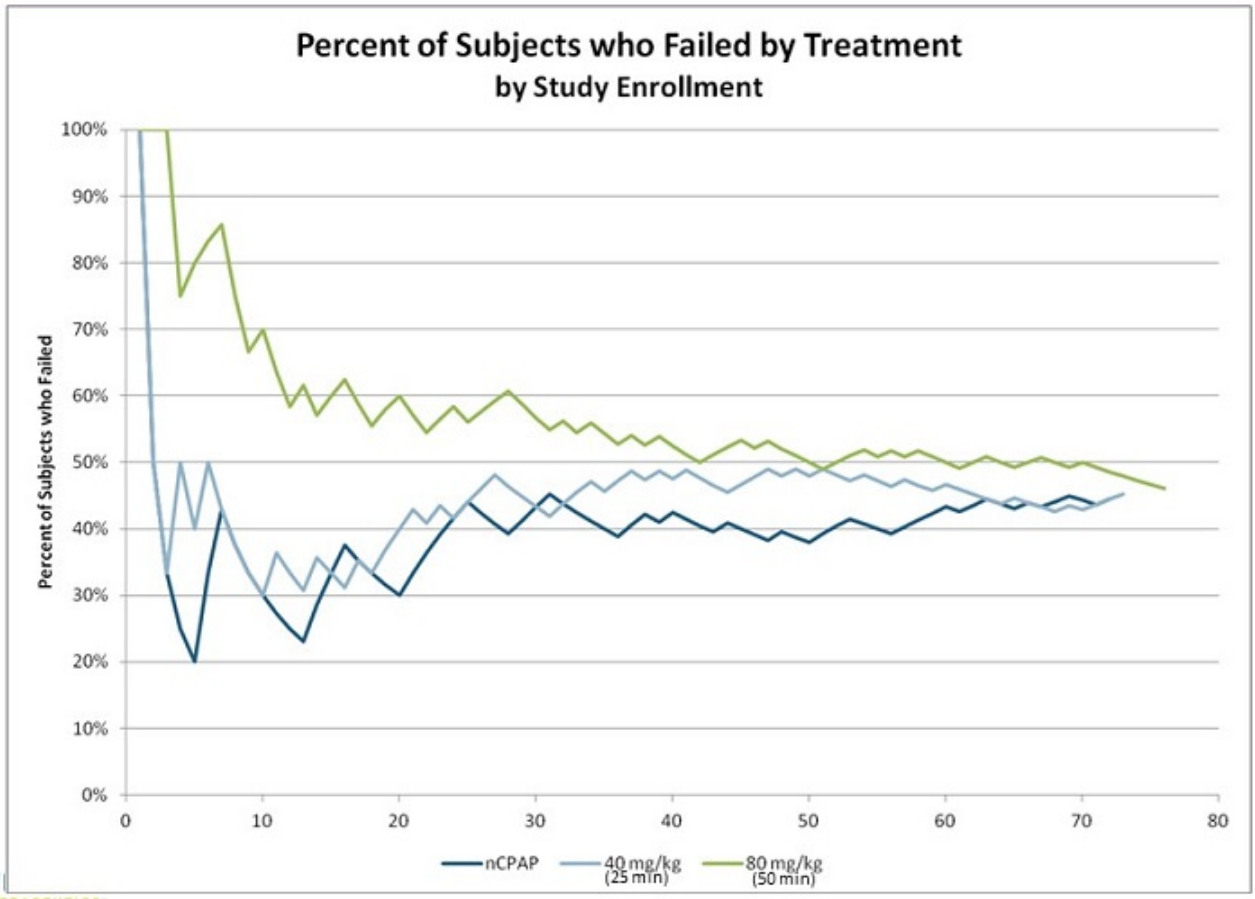
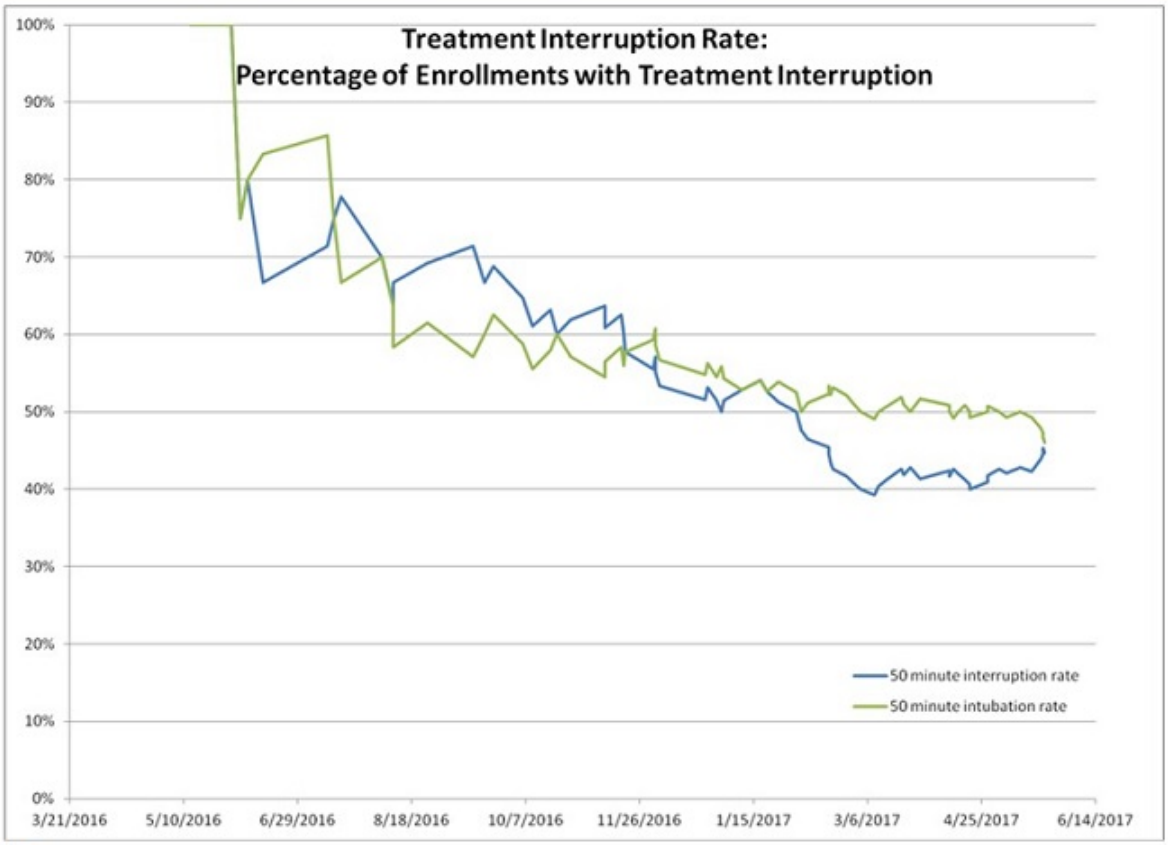
Clinical Management of Treatment Interruptions

1. Confirmed this was a non-safety related issue
   - Device worked as designed to shut down treatment upon sensing back pressure due to clogged filter (which occurs at the machine and does not affect the patient)
   - Data Safety Monitoring Board (and Steering Committee) reviewed
2. With Battelle, our device development partner, we identified the root cause (a specific batch of filters with a higher tendency to clog)
3. We remained blinded to any potential effect and implemented training and guidance to mitigate the issue at the sites
   - Implemented protocol clarification with supplemental dosing guidance to achieve minimum 90% of target dose for 50 minute treatment.
   - communicated to sites to use devices sourced with a different batch of filters (when available) for 50 minute (80 mg) treatment
4. It was believed that with dosing guidance to ensure complete dosing, there would be minimal effect on the results. In examining the 2b results, the filter-related interruptions and the corrective actions appear to have had an impact
5. This issue is believed to be corrected (and recently verified) in our current NextGen (Phase 3 / Commercial) system completing validation

nCPAP Failure Rate Over Time by Treatment Group



80 mg/kg (50 min) Treatment Interruptions and nCPAP Failures Over Time



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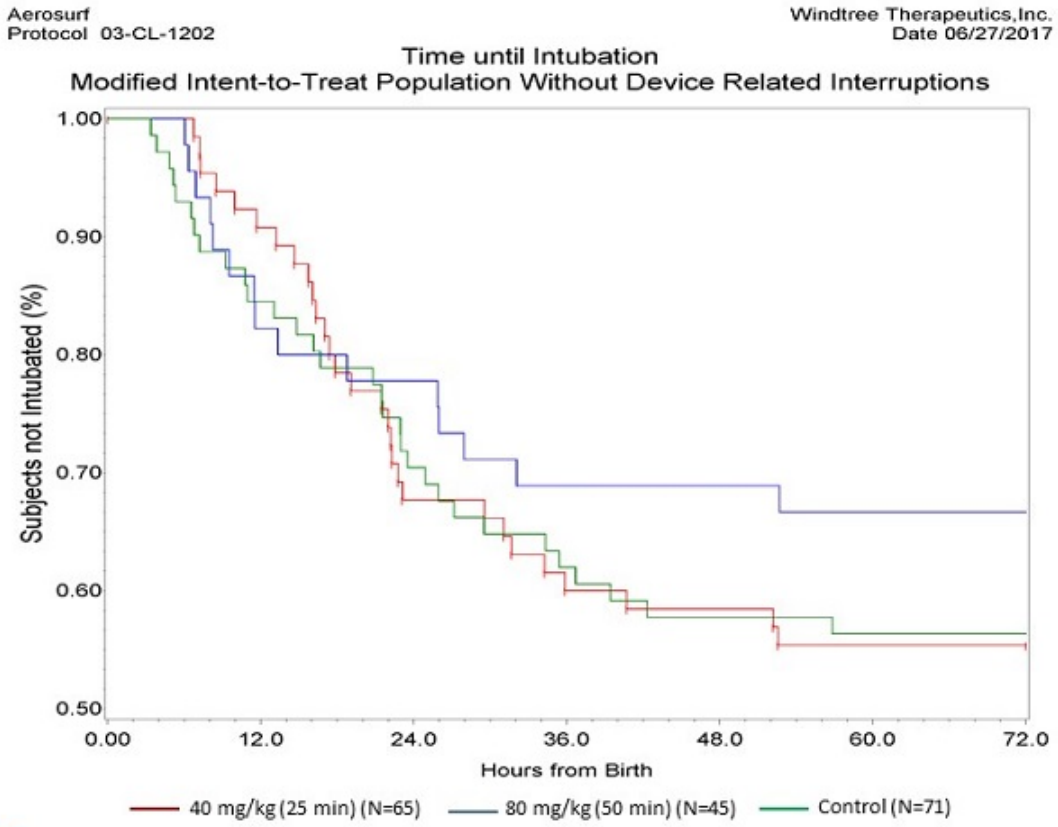
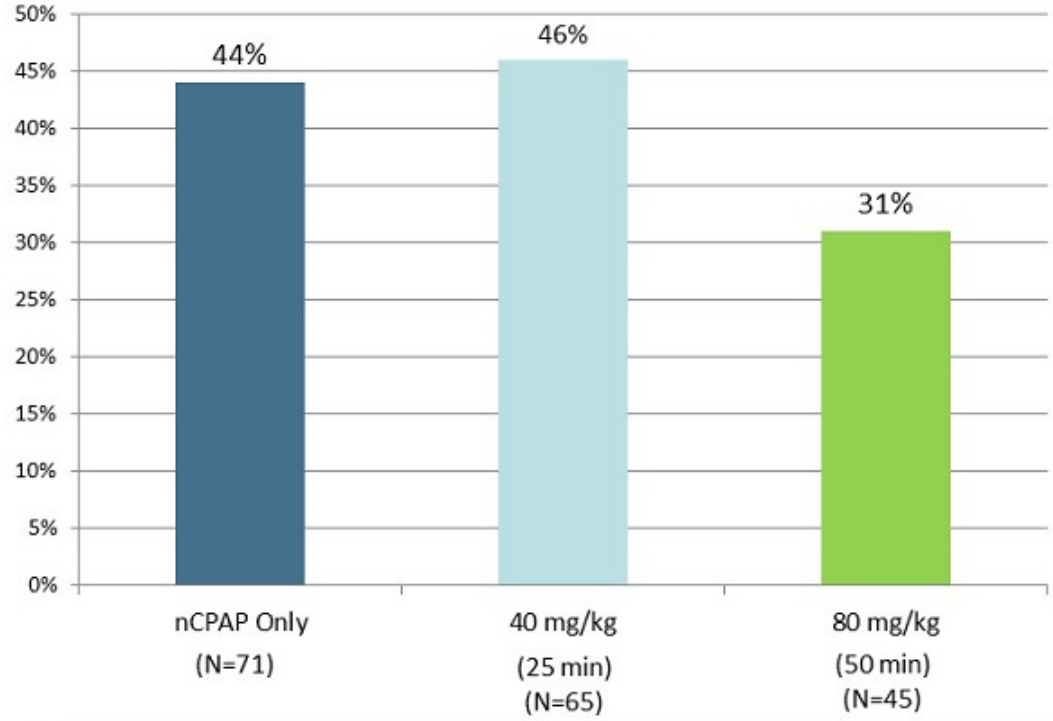
Time to nCPAP Failure (from birth)
mITT Without Treatment Interruptions



Incidence of nCPAP Failure

mITT Without Treatment Interruptions



AEROSURF® treated patients in the 50 min dose group without treatment interruptions experienced a 13% absolute reduction or a 30% relative reduction in nCPAP failure compared to control

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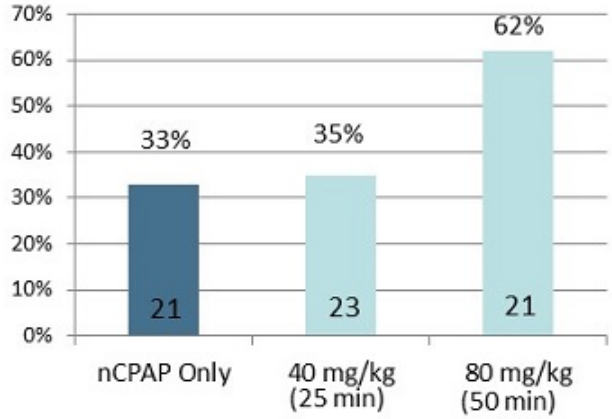
Incidence of nCPAP Failure Across the Two Highest Enrolling Countries (*mITT*)

Higher treatment interruptions
(higher impaired filter lots)

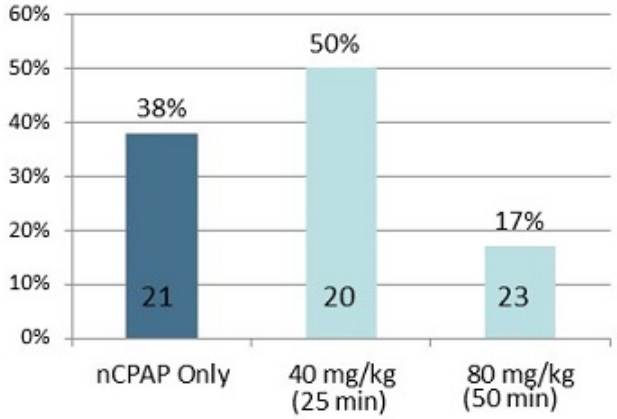
Poland



Poland		interrupted			not interrupted		
Group	total	fail	total		fail	total	
80	**21**	**11**	**13**	**85%**	**2**	**8**	**25%**
40	23	2	3	67%	6	20	30%

Lower treatment interruptions
(no impaired filter lots)

US



AEROSURF® treated patients in **the 50 min dose** group experienced a 21% absolute reduction or a **56% relative reduction in nCPAP failure compared to control**

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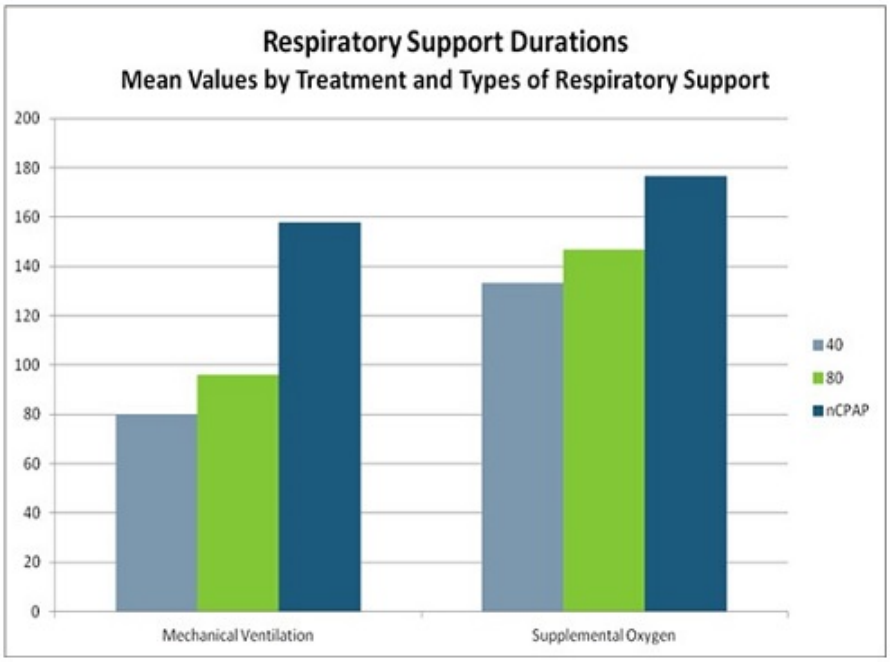
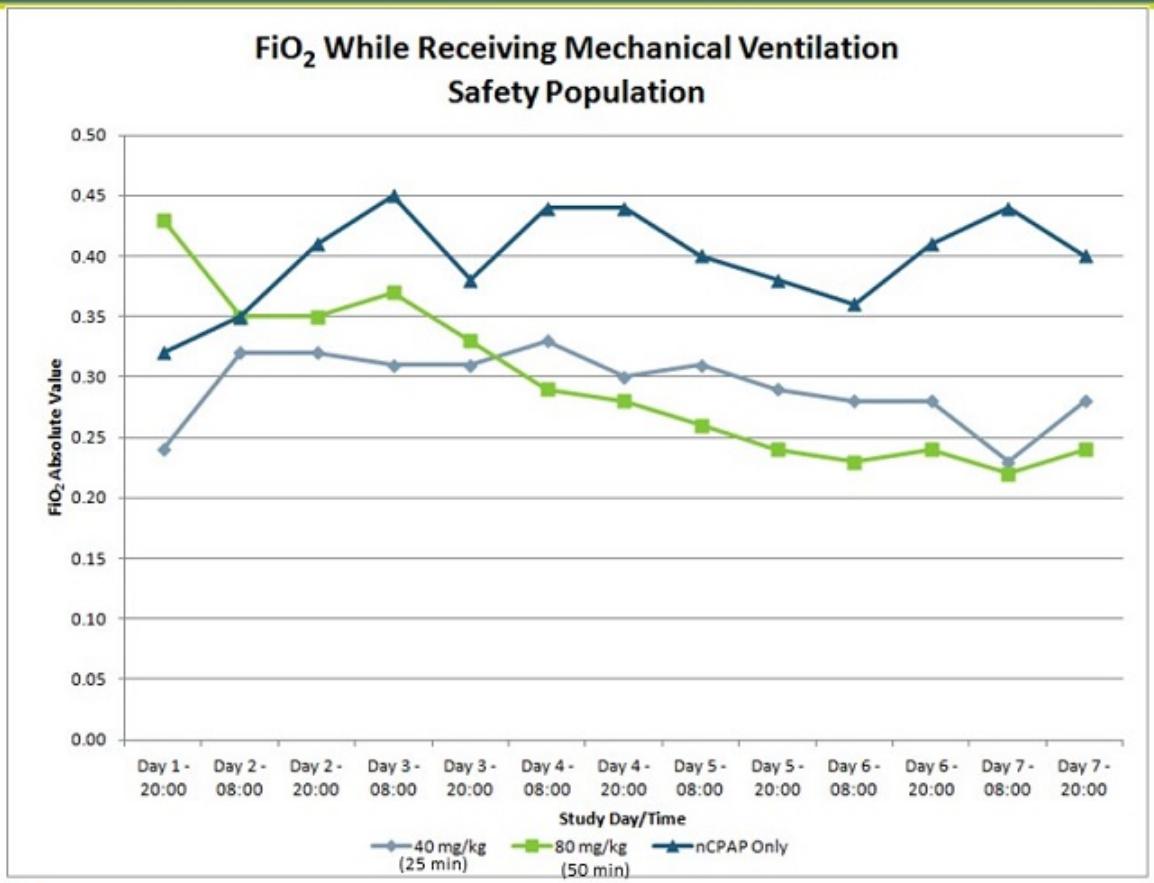
Respiratory Support in Patients Who Failed nCPAP



In patients who failed CPAP and required intubation and mechanical ventilation, AEROSURF treated patients appeared to require shorter duration of mechanical ventilation and time on supplemental oxygen

Time On Mechanical Ventilation and Supplemental Oxygen



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Safety & Tolerability Profile

- The adverse event and serious adverse event profile was similar across the 3 groups
- Complications of prematurity were also similar

	40 mg/kg (25 min)	80 mg/kg (50 min)	nCPAP Only
Acquired Sepsis	13 (19%)	14 (20%)	16 (25%)
Air Leak	7 (10%)	7 (10%)	9 (14%)
Apnea	31 (45%)	24 (34%)	24 (37%)
PVL	1 (1%)	1 (1%)	1 (2%)
PDA	18 (26%)	25 (36%)	22 (34%)
IVH	8 (12%)	9 (13%)	9 (14%)
NEC	2 (3%)	6 (9%)	2 (3%)
ROP	2 (3%)	7 (10%)	6 (9%)
BPD	7 (10%)	8 (11%)	9 (13%)
Alive w/o BPD	83%	79%	75%

- The safety and tolerability profile of AEROSURF treated patients both with and without treatment interruptions was similar

AEROSURF® Phase 2b Summary

- The planned top line analysis of the primary endpoint did not show a treatment effect
- When dosed as intended, the 50 minute dose achieved a positive treatment effect on the upside of our target and replicates the results in our 2a study (executed in the U.S. in similar gestational age infants)
- For AEROSURF patients who experienced nCPAP failure, the time on mechanical ventilation and supplemental oxygen, as well as level of required oxygen support, were lower compared to control patients who experienced nCPAP failure
- AEROSURF's safety and tolerability continues to be similar to nCPAP alone
  - The safety profile may support the clinical pursuit of decreasing time to treatment and faster time for repeat dosing when necessary
- While analysis of data is ongoing, the phase 2b trial has increased our learnings for future development and achieved a number of important clinical objectives for demonstrating high dose treatment effect and the potential to replicate desired results
- In the weeks to come, we will work with regulators to solidify a regulatory and clinical plan to incorporate the new, next generation device (the design of which mitigates the issues we experienced with the prototype device set up) for the next step phase 3 program

AEROSURF® Phase 2b

Q & A