Therapeutics MD°

Jefferies Global Healthcare Conference

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Forward-Looking Statements

This presentation includes forward-looking statements covered by the safe harbor provision of the Private Securities Litigation Reform Act of 1995, including predictions, estimates, and other information that might be considered forward-looking. While these forward-looking statements represent TherapeuticsMD, Inc.'s ("TherapeuticsMD," "we," "us," and "our") current judgment on what the future holds, they are subject to risks and uncertainties, many of which are outside our control, that could cause actual results to differ materially from the results discussed in the forward-looking statements.

You are cautioned not to place undue reliance on these forward-looking statements, which reflect our opinions only as of the date of this presentation. Please keep in mind that we are not obligating ourselves to revise or publicly release the results of any revision to these forward-looking statements in light of new information, future events, or otherwise.

Throughout this presentation, we will attempt to present some important factors relating to our business that may affect our predictions. You should also review our most recent Form 10-K and our other filings with the Securities and Exchange Commission, for a more complete discussion of these factors and other risks, particularly under the heading "Risk Factors." A PDF copy of our SEC filings, press releases and financial tables can be viewed and downloaded on the TherapeuticsMD website: **www.therapeuticsmd.com/InvestorRelations.aspx.**



TXMD Company History

- Founded in May of 2008
- **S** Originally a prenatal vitamin company
- Recently listed on NYSE MKT under "TXMD"
- Shares outstanding: approximately 130 million
- Approximately \$40 million in cash; no long-term debt
- Strong board with blue-chip institutional holders
 - Gov. Tommy Thompson, Jules Musing, Ernest Mario (investor)



Innovative Women's Healthcare Company

Two late-stage 505(b)(2) proposed hormone therapy ("HT") products targeting a multi-billion dollar U.S. market ⁽¹⁾⁽²⁾

- Bioidentical combination of estradiol + progesterone and lower-dose bioidentical progesterone
- Set to begin pivotal Phase 3 clinical trials

	2013E	2014E	2015E	2016E	U.S. Sales (est.)(\$mm) ⁽¹⁾⁽²⁾
Combination: 17β Estradiol + Progesterone					\$2,000
Oral Progesterone					\$300

Novel estradiol pipeline product in development



History of Hormone Therapy

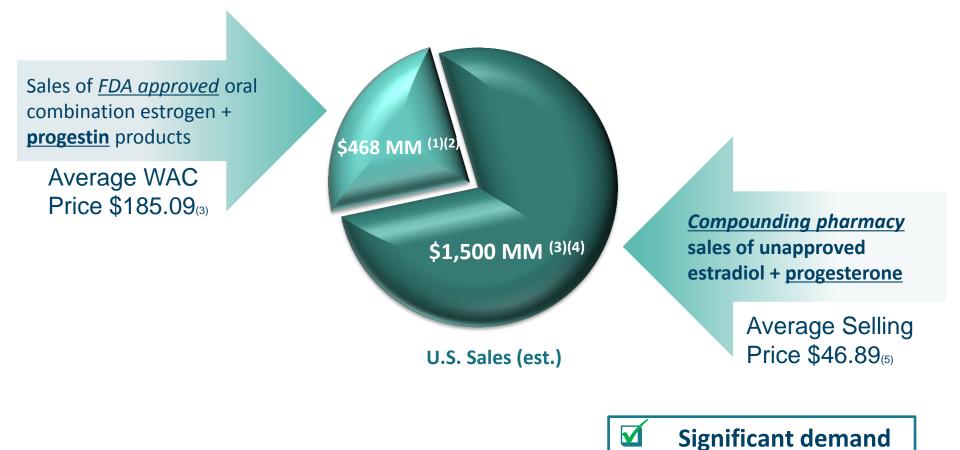
2002 Women's Health Initiative (WHI) Study

- Lower doses = lower side effect profile
- Estrogen + <u>Progestin</u> (Prempro) arm had a 22% increase in breast cancer vs. Estrogen alone arm

B Resulting Hormone Prescribing Trends

- Start with the lowest effective dose
- Progesterone (bioidentical) popularity over Progestins (non-bioidentical)
- Bioidentical (exact molecular structure of human Estrogen and Progesterone) sales sky rocket

HT Combination Market Landscape



- (1) Phast Prescription Monthly by Source Healthcare Analytics.
- Based on last twelve months sales through June 30, 2012, and estimated sales from July 1 through December 31, 2012. (2)
- (3) Estimate per Wulf Utian, Executive Director Emeritus and Honorary Founding President of NAMS.
- Dr. Loyd Allen Jr., Editor-in-Chief of the International Journal of Pharmaceutical Compounding, stated the U.S. drug compounding (4) market is \$10-\$12 billion; and Tom Murry, Executive Director of the Pharmaceutical Compounding Accreditation Board, said HT for post-menopausal women is by far the largest of four primary segments served by the compounding industry. (5)
 - 134 Compounding Pharmacies Survey in 34 States

Bioidentical Progesterone vs. Non-Bioidentical Progestin

The Market understands the benefits of bioidentical HT

Side Effect ⁽¹⁾	Bioidentical Natural Progesterone	Non-Bioidentical Progestins (MPA, NETA, drosperinone)	
Breast cancer	More favorable profile (E3N-EPIC study)	Increased risk	
Cardiovascular	More favorable profile (PEPI trial)	Increased risk of MI, stroke, VTE	
Lipid profile	More favorable profile (PEPI trial)	Less favorable effects on lipid profile (cholesterol, HDL, LDL, triglycerides)	
Glucose / insulin	Improved carbohydrate metabolism (PEPI trial)	Deterioration of glucose tolerance or hyperinsulemia or both	
Sleep / mood	Improved sleep efficiency ⁽²⁾	No benefit on sleep properties	
Quality of life Improvement in symptoms and overall satisfaction with bioidentical progesterone HT compared to MPA regimen ⁽³⁾			
(1) Alone or in combination with estrogen. (2) Caufriez, Anne, Rachel Leproult, Mireille L'Hermite-Bale´riau, Myriam Kerkhofs, and Georges Copinschi. "Progesterone Prevents Sleep Disturbances and Modulates GH, TSH, and Melatonin Secretion in Postmenopausal Women." J Clin Endocrinol Metab 96.4 (2011): 614-23. 7 (3) Fitzpatrick, Pace, and Wita. "Comparison of Regimens Containing Oral Micronized Progesterone or Medroxyprogesterone Acetate on Quality of Life in Postmenopausal Women: A Cross- 7			

(3) Fitzpatrick, Pace, and Wita. "Comparison of Regimens Containing Oral Micronized Progesterone or Medroxyprogesterone Acetate on Quality of Life in Postmenopausal Women: A Cross-Sectional Survey." J Womens Health Gend Based Med 9.4 (2000): 381-87.

Sonverted (API) from solid / crystalline to a <u>New Liquid Drug Form</u>

- Estrace (RLD) is a tablet 0.5 mg, 1.0 mg, and 2.0 mg
- Prometrium (RLD) is in suspension 100 mg and 200 mg

New solubilized drug form

- Achieves FDA requirements of uniformity and stability
- Improved functional effects of API(s)
- Enabling new combinations, routes, and dosages







Building an Extensive Patent Estate

Novel Drug Form Based Approach

- Solubilized API in combination and stand-alone drug products for HT indications
- Enabling platform technology for delivery of bioidenticals to variety of dosage forms and routes of administration (softgel oral, suppository, transdermal, etc.)

Multi-layered Patent Strategy

Novel dosage forms, improved PK profiles (lowest effective dose, increased bioavailability) relative to RLD, reduced side effect profile, and formulation advancements (solvent systems, chemical stability, ratios, ranges, and functional effects)

Senate HELP Bill 959 on Compounding

New England Compounding Center

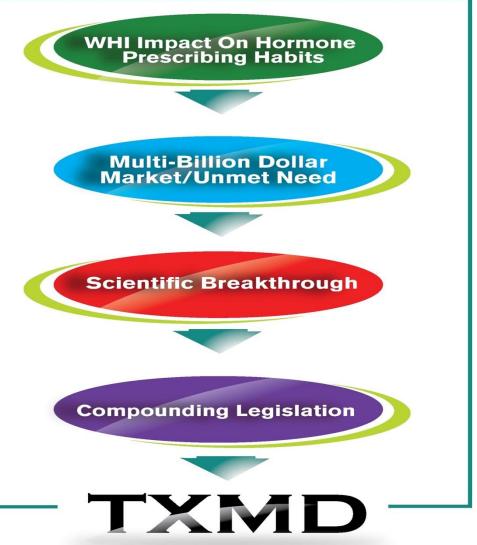
- Response to Meningitis outbreak, killed 50 and made over 700 patients sick
- B Multiple other cases of unsafe drug sales by other compounding pharmacies

Senate Bill Highlights (1)

- Establishes clear FDA oversight funded by compounding pharmacy registration fees
- Prohibits compounding of certain drug products, including those identified by regulation as being demonstrably difficult to compound (such as complex dosage forms and biologics), marketed FDA-approved drugs that are not in shortage"

Market Forces Converge

- External market changing events
 - 🔁 WHI
 - Proposed legislative changes
- Internal scientific
 breakthrough
- Significant shifts favor TXMD



Why Hormone Therapy?

- HT is projected to be the largest growth segment in the overall women's health drug market
- Demographics driving strong growth fundamentals
 - By 2015, nearly half the women in America will be of menopausal age ⁽¹⁾
 - Women will spend more than a third of their life in menopause and post-menopause

Very attractive commercial dynamics

- Segment of the market that lacks innovation
- **B** Relatively little promotional activity in the space
- Opportunity to capture market share



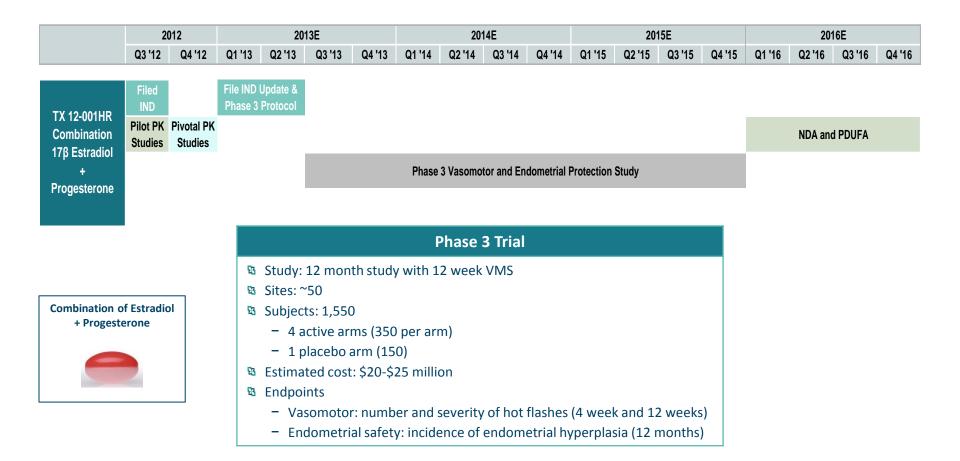
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(1) U.S. Census Bureau.

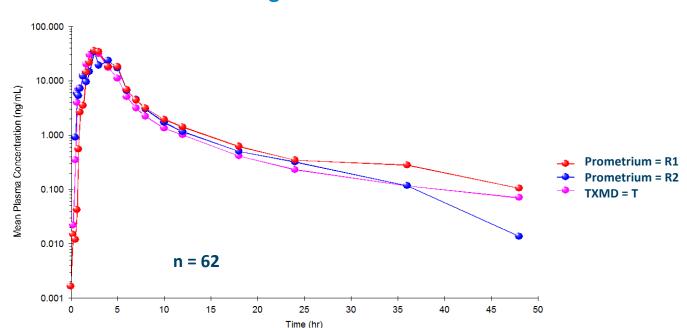
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Combination Product

TX 12-001HR Combination— Proposed Phase 3 Study



TX 12-001HR Estradiol 2 mg / Progesterone 200 mg (combination) vs. Estrace[®] 2 mg + Prometrium[®] 200 mg (separate tablets)



Progesterone Results⁽¹⁾

95% Upper Confidence Limit for PK Parameter

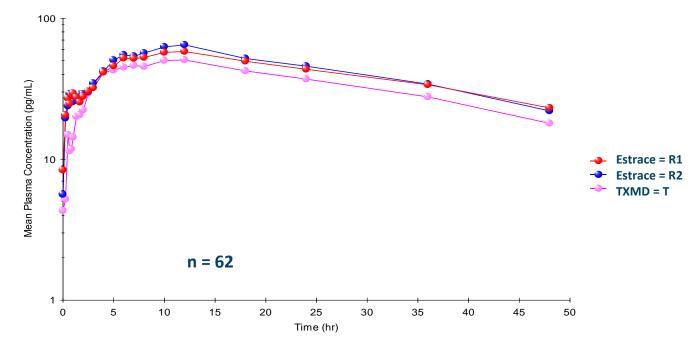
Parameter	Point Estimate T/R Ratio	Within Subject Std. Deviation	Upper 95% Confidence Bound
C _{max}	1.16	1.179	-0.785
AUC _{0-t}	1.05	0.956	-0.542

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(1) Semilog plots of mean plasma concentrations over time for Progesterone.

TX 12-001HR Estradiol 2mg / Progesterone 200 mg (combination) vs. Estrace[®] 2m g + Prometrium[®] 200 mg (separate tablets)

17β Estradiol Results ⁽¹⁾



95% Confidence Interval for PK Parameter

Parameter	Point Estimate T/R Ratio	Within Subject Std. Deviation	Upper 95% Confidence Bound
C _{max}	0.88	0.344	-0.040
AUC _{0-t}	0.93	0.409	-0.089

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(1) Semilog plots of mean plasma concentrations over time for Free Estradiol.

TX 12-001HR Combination Potential Benefits

Drug Improvement	General Benefits	Patient Benefits
Receive FDA approved indication	FDA indication / safety and quality assurance	Insurance coverageSafety, quality, and stability
New lower effective doses	Reduced blood levelsBetter side effect profile	Improved safety
Improved safety profile vs. non-bioidentical progestin	 Reduced breast cancer risk Improved cardiovascular and lipid profile 	Confidence in treatment regimen
No peanut oil	Non-allergenicExcellent for all patient profiles	No worries about potential allergies
Combined pill vs. 2 pills (E+P sold separately today)	Less risk of dosing errors	One co-payIncreased compliance

FDA Approved Products in Use Lack Innovation

All FDA approved products in use contain <u>non-bioidentical</u> progestins

Product	Progestin	U.S. Sales (est.) (\$mm)	Intl Sales (\$mm) (4)	Company
17β Estradiol + NETA / Drospirenone (Activella / FemHRT / Angeliq / others)	Non-bioidentical	\$178 ⁽¹⁾⁽²⁾		WARNER NOVO NOrdisk Bayer
Premarin + MPA (Prempro / Premphase)	Non-bioidentical	290 ⁽¹⁾⁽²⁾		Pfizer
Estradiol + Progesterone (custom compounded)	Untested Bioidentical	1,500 ⁽³⁾		Not FDA approved
Total Oral Combination Sales		\$1,968	\$489	

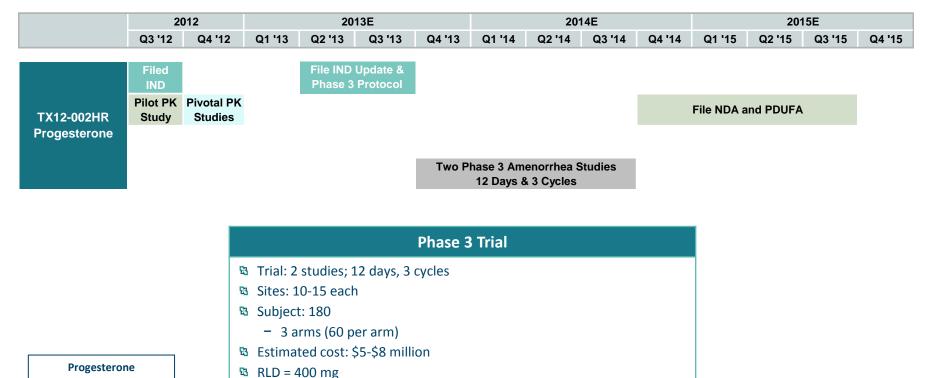
Notes: All FDA approved combination products in use contain a non-bioidentical progestin.

- Phast Prescription Monthly by Source Healthcare Analytics. (1) Therapeutics MD
 - Based on last twelve months sales through June 30, 2012, and estimated sales from July 1 through December 31, 2012. (2)
 - Estimate per Wulf Utian, Executive Director Emeritus and Honorary Founding President of NAMS. (3)
 - (4) IMS Data

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New Lower Dose Progesterone

TX 12-002HR Progesterone— Proposed Phase 3 Study



Endpoints

- Withdrawal bleeding and secretory change

TX 12-002HR Progesterone Candidate

Conducted PK studies in accordance with FDA requirements

TXMD <u>150 mg</u> test dose found to be bioequivalent to <u>200 mg</u> Prometrium[®]

Summary evaluations of baseline-corrected Progesterone results for a theoretical

150 mg test capsule vs. 200 mg Prometrium[®] capsule

Parameter	Point Estimate T/R Ratio	Within Subject Std. Deviation	Upper 95% Confidence Bound
C _{max}	1.03	1.133	-0.747
AUC _{0-t}	0.96	0.891	-0.465

TX 12-002HR Progesterone— Potential Benefits

Drug Improvement	General Benefits	Patient Benefits
New lower effective doses	 Lower first-pass metabolites Better side effect profile 	Less somnolenceImproved safety
		. ,
Improved safety profile vs. non-bioidentical progestin	 Reduced breast cancer risk Improved cardiovascular profile Improved lipid profile 	Confidence in treatment regimen
No peanut oil	Non-allergenicExcellent for all patient profiles	No worries about potential allergies

Natural Progesterone Dominates

Product	Progestin	U.S. Sales (est.) (\$mm) ⁽¹⁾⁽²⁾	INTL Sales (3)	Company	Generic Available
Provera [®] (medroxyprogesterone acetate)	Non- bioidentical	\$26			\checkmark
Aygestin [®] (norethindrone acetate)	Non- bioidentical	45		573170	✓
Prometrium[®] (micronized progesterone)	Bioidentical	247		Abbott A Promise for Life BESINS HEALTHCARE	\checkmark
Total Oral Progestin Sales		\$318	\$600		

⁽¹⁾ Phast Prescription Monthly by Source Healthcare Analytics.

⁽²⁾ Based on last twelve months sales through June 30, 2012, and estimated sales from July 1 through December 31, 2012.
(3) IMS Data



TX 12-004HR Estradiol Product— Vulvar / Vaginal Atrophy

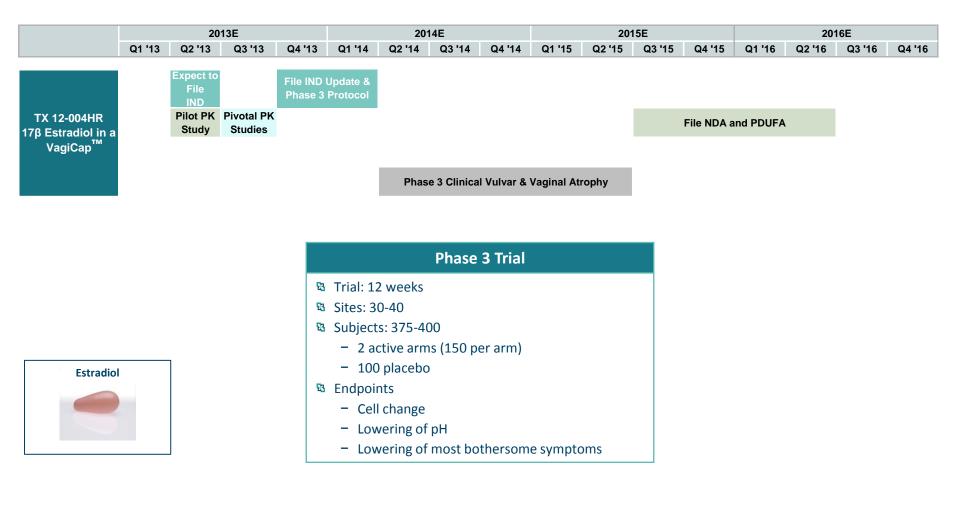
Product	Compound	U.S. Sales (est.) (\$mm) ⁽¹⁾⁽²⁾	Problems
Premarin [®] Cream	Conjugated equine vaginal estrogen	\$265	 Equine source Non-bioidentical Messy Reusable plungers
Vagifem [®] Tablets Estrace [®] Cream	Vaginal estradiol	\$558	 Messy Reusable plungers Difficult to use Continuous-use mechanical device
Total Sales		\$823	

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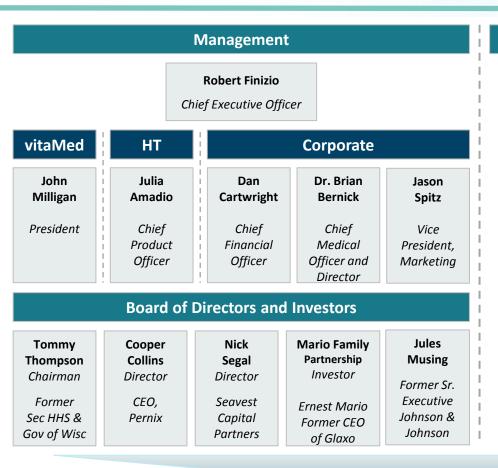
(1) Phast Prescription Monthly by Source Healthcare Analytics.

(2) Based on last twelve months sales through June 30, 2012, and estimated sales from July 1 through December 31, 2012.

TX 12-004HR Proposed Estradiol Vaginal Suppository—Proposed Phase 3 Study



Experienced Management and Drug Development Team



Drug Development Team

- **3** Julia Amadio and James Pickar, M.D., F.A.C.O.G.
 - Led development and launch of Prempro[®], Premphase[®], CombiPatch[®], Alesse[®], and Crinone[®], among others

Lisa Rarick, M.D. and Daniel Shames, M.D.

 Former division Director of Reproductive and Urologic Products for FDA CDER

Fred Sancilio, Ph.D.

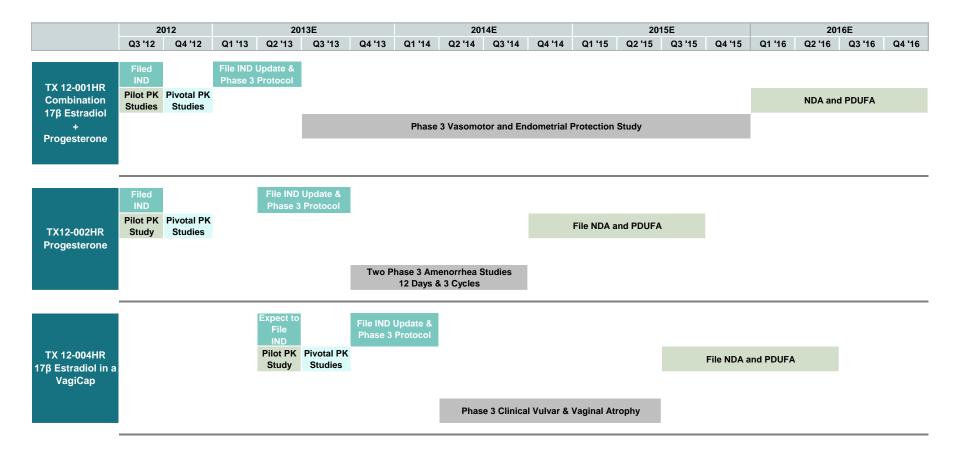
 Former founder and president of AAI and the innovator of multiple hormone products

Steve Fontana, J.D.

- Author of the original estradiol patents
- **Bill Mulholland**, J.D.
 - Lead patent attorney; previously, IP counsel at Pfizer

Proven team with a successful track record of creating shareholder value and developing some of the most successful products in the HT and birth control space TherapeuticsMD

Potential Milestones



Investment Highlights

FRA	NKLIN. TEMPLETON. INVESTMENTS WELLINGTON MANAGEMENT
1	Novel late-stage hormone therapy candidates
2	Clear pivotal trial endpoints / low risk regulatory pathway
3	Compelling, growing market opportunity, especially with recent concerns regarding compounders
4	Recently completed \$50 million equity financing
5	Robust, growing patent estate

-PINE RIVER

BROADFIN



RA CAPITAL