**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): July 3, 2013**

# PROLOR BIOTECH, INC.

(Exact Name of Registrant as Specified in Its Charter)

| **Nevada** | **001-34676** | **20-0854033** |
|---|---|---|
| **(State or Other Jurisdiction of Incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |

**7 Golda Meir Street**
**Weizmann Science Park**
**Nes-Ziona, Israel 74140**
**(Address of Principal Executive Office)**

Registrant's telephone number, including area code (866) 644-7811

(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 July 3, 2013, PROLOR Biotech, Inc., a Nevada corporation (the "Company"), issued a press release announcing that it will present new results from preclinical studies of its long acting clotting Factor VIIa (Factor VIIa-CTP) at the XXIV Congress of the International Society of Hemostasis and Thrombosis (the "ISTH Congress"), which is being held in Amsterdam. The Company will commence its presentation at 9:15 a.m. local time on July 4, 2013. A copy of the press release is filed herewith as Exhibit 99.1 to this Current Report on Form 8-K and incorporated by reference in this Item 8.01.

At the ISTH Congress, the Company will additionally present a slide presentation, a copy which is filed herewith as Exhibit 99.2 to this Current Report on Form 8-K and incorporated by reference in this Item 8.01.

**ITEM 9.01. Financial Statements and Exhibits.**

**(d) Exhibits.**

| Exhibit Number | Description |
|---|---|
| 99.1 | Press Release, dated July 3, 2013 |
| 99.2 | Slide Presentation |

**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.

**PROLOR BIOTECH, INC.**

Date: July 3, 2013

By: /s/ Shai Novik
Shai Novik
President

**EXHIBIT INDEX**

| Exhibit Number | Description |
|---|---|
| 99.1 | Press Release, dated July 3, 2013 |
| 99.2 | Slide Presentation |

**PROLOR BIOTECH TO PRESENT POSITIVE RESULTS FROM PRECLINICAL STUDIES OF LONG-ACTING CLOTTING FACTOR Vlla-CTP AT ISTH 2013**

***--New Data Show a Simple Subcutaneous Injection of Factor Vlla-CTP Could Potentially Replace Current Therapies Administered Via Infusion--***

**Amsterdam, Netherlands and Nes-Ziona, Israel** – **July 3, 2013** – PROLOR Biotech, Inc. (NYSE MKT: PBTH), today announced that the company will present new results from preclinical studies of its long-acting clotting factor VIIa (Factor Vlla-CTP), a next-generation investigational therapy in advanced preclinical development for the potential treatment of hemophilia. The data provide further evidence that Factor VIIa-CTP has the potential to be administered by subcutaneous (SC) injection as well as intravenously (IV), which would facilitate its prophylactic use by patients on an ongoing basis. The study results will be discussed in an oral presentation at the XXIV Congress of the International Society of Hemostasis and Thrombosis (ISTH).

Currently available commercial factor VIIa must be administered through IV infusion, which can be onerous for patients. This limits its use for prophylactic treatment and can require frequent administrations if patients are treated only "on demand" when a bleeding episode occurs.

The new preclinical results being presented at the ISTH Congress further confirm the efficacy of PROLOR's long-acting Factor VIIa-CTP and show that it has the potential to be administered using a simple SC injection. The combination of a long-acting product coupled with the ability to be administered by SC injection could change the way that factor VIIa is used, potentially allowing individuals with hemophilia to self-administer the drug at home on a prophylactic basis, improving their quality of life and potentially reducing the need for on-demand treatment of bleeding episodes.

Dr. Abraham Havron, CEO of PROLOR, commented, "We have previously presented data in animal models of hemophilia showing that Factor Vlla-CTP demonstrated long-acting properties compared to commercially available factor VIIa. These new data reflect our extensive recent work confirming those data and also assessing the potential of hGH-CTP to be administered by SC injection, which could be transformative for some hemophilia patients. Based on these exciting results, we expect to initiate two independent clinical programs for Factor Vlla-CTP in 2014—one for on-demand and prophylactic treatment of hemophilia using the IV route and a second for prophylactic treatment using the SC route."

The data will be presented by Dr. Gili Hart, Vice President, Pre-Clinical Development and Clinical Pharmacology at PROLOR and head of the company's long-acting clotting factors program. Dr. Hart's presentation, "A long-acting FVIIa-CTP proposing an improved prophylactic and on-demand treatment for hemophilic patients following SC and IV administration - evaluation in animal models," will be presented on July 4, 2013, at 9:15 am local time. The XXIV ISTH Congress is being held June 29-July 4, 2013, in Amsterdam. For more information, visit http://www.isth2013.org.

**About Hemophilia**

Patients with hemophilia do not produce adequate amounts of the clotting factors that are necessary for effective blood clotting. In severe hemophiliacs even a minor injury can result in blood loss that may continue for days or weeks, with the potential for debilitating permanent damage to joints and other organs and premature death. According to the World Health Organization, more than 400,000 people worldwide have hemophilia. Commercially available recombinant clotting factors have enabled many hemophiliacs to live near-normal lives, but frequent injections, infusions and/or blood transfusions may be required.

**Planned PROLOR Merger with OPKO Health**
On April 24, 2013, OPKO Health, Inc. (NYSE: OPK) and PROLOR Biotech announced that the companies had signed a definitive merger agreement under which OPKO will acquire PROLOR in an all-stock transaction. Under the terms of the agreement, which has been approved by the boards of directors of both companies, holders of PROLOR common stock will receive 0.9951 shares of OPKO common stock for each share of PROLOR stock. PROLOR and OPKO expect the transaction to be completed during the second half of 2013. Closing of the transaction is subject to certain conditions, including the approval of the merger agreement by PROLOR's stockholders, approval of the issuance of the share consideration by OPKO's stockholders, the receipt of antitrust approval and other customary closing conditions.

**Additional Information and Where to Find It**
This communication does not constitute an offer to sell or the solicitation of an offer to buy any securities or a solicitation of any vote or approval nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. In connection with the proposed merger between PROLOR and OPKO, OPKO has filed with the Securities and Exchange Commission (the "SEC") a Registration Statement on Form S-4 that includes a proxy statement of OPKO and PROLOR and a prospectus of OPKO. Stockholders of OPKO and PROLOR are urged to read the joint proxy statement/prospectus regarding the proposed transaction, as well as other documents filed with the SEC, because they contain important information. Stockholders of OPKO and PROLOR may obtain a copy of the joint proxy statement/prospectus, as well as other filings containing information about PROLOR and OPKO, without charge, at the SEC's website (www.sec.gov). Stockholders of OPKO and PROLOR may also obtain copies of all documents filed with the SEC, without charge, by directing a request to Shachar Shlosberger, PROLOR Biotech, Inc., 7 Golda Meir Street, Weizmann Science Park, Nes-Ziona, Israel 74140, telephone (+972) 8-930-0051, or Steven D. Rubin or Juan F. Rodriguez, OPKO Health, Inc., 4400 Biscayne Blvd., Miami, Florida, telephone (305) 575-4100.

Investors may obtain copies of all documents filed with the SEC regarding this transaction, free of charge, at the SEC's website (www.sec.gov). They may also obtain these documents, free of charge, from OPKO's website (www.opko.com) or from PROLOR's website (www.prolor-biotech.com).

**Participants in the Merger Solicitation**
PROLOR, OPKO and their respective directors and executive officers may be deemed to be participants in the solicitation of proxies from the stockholders of PROLOR and OPKO in connection with the proposed transaction. Information about PROLOR's directors and executive officers is set forth in its proxy statement for its 2013 Annual Meeting of Stockholders, which was filed with the SEC on April 25, 2013. These documents are available free of charge at the SEC's website at www.sec.gov, or by going to PROLOR's Investor Relations page on its corporate website at www.prolor-biotech.com. Information about OPKO's directors and executive officers is set forth in Amendment No. 1 to its Annual Report on Form 10-K for the year ended December 31, 2012, which was filed with the SEC on April 29, 2013. These documents are available free of charge at the SEC's website at www.sec.gov, or by going to OPKO's Investor Relations page on its corporate website at www.opko.com. Additional information regarding the interests of participants in the solicitation of proxies in connection with the transaction will be included in the joint proxy statement/prospectus.

**About PROLOR**
PROLOR Biotech, Inc. is a clinical stage biopharmaceutical company applying unique technologies, including patented CTP technology and its long-acting reversible-pegylation technology, primarily to develop longer-acting proprietary versions of already approved therapeutic proteins that currently generate billions of dollars in annual global sales. The CTP technology is applicable to virtually all proteins. PROLOR is developing a long-acting version of human growth hormone, which is in a Phase III clinical trial. It also is developing long-acting versions of factor VIIa and factor IX for hemophilia and a GLP-1/Glucagon dual receptor agonist peptide for diabetes and obesity, all of which are in preclinical development. For more information, visit http://www.prolor-biotech.com.

***Safe Harbor Statement****: This press release contains forward-looking statements, which may be identified by words such as "expects," "plans," "projects," "will," "may," "anticipates," "believes," "should," "would", "intends," "estimates," "suggests," "has the potential to" and other words of similar meaning, including statements regarding the results of current clinical studies and preclinical experiments and the effectiveness of PROLOR's long-acting protein programs, which are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Investors are cautioned that forward-looking statements involve risks and uncertainties that may affect PROLOR's business and prospects, including the risks that PROLOR may not succeed in generating any revenues or developing any commercial products, including any long-acting versions of human growth hormone, erythropoietin, interferon beta, GLP-1 and other products; that the long-acting products in development may fail, may not achieve the expected results or effectiveness and/or may not generate data that would support the approval or marketing of these products for the indications being studied or for other indications; that ongoing studies may not continue to show substantial or any activity; that the actual dollar amount of any grants from Israel's Office of the Chief Scientist is uncertain and is subject to policy changes of the Israeli government, and that such grants may be insufficient to assist with product development; and other risks and uncertainties that may cause results to differ materially from those set forth in the forward-looking statements. The results of clinical trials in humans may produce results that differ significantly from the results of clinical and other trials in animals. The results of early-stage trials may differ significantly from the results of more developed, later-stage trials. The development of any products using the CTP platform technology could also be affected by a number of other factors, including unexpected safety, efficacy or manufacturing issues, additional time requirements for data analyses and decision making, the impact of pharmaceutical industry regulation, the impact of competitive products and pricing and the impact of patents and other proprietary rights held by competitors and other third parties. In addition to the risk factors described above, investors should consider the economic, competitive, governmental, technological and other factors discussed in PROLOR's filings with the Securities and Exchange Commission. The forward-looking statements contained in this press release speak only as of the date the statements were made, and we do not undertake any obligation to update forward-looking statements, except as required under applicable law.*

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# MOD-5014 -A Long Acting FVIIa

NYSE Amex: PBTH

**Non-Confidential**

Disclosures of: **GILI HART**

| | |
|---|---|
| Employment | PROLOR BIOTECH |
| Research support | No conflict of interest to disclose |
| Scientific advisory board | No conflict of interest to disclose |
| Consultancy | No conflict of interest to disclose |
| Speakers bureau | No conflict of interest to disclose |
| Major stockholder | No conflict of interest to disclose |
| Patents | No conflict of interest to disclose |
| Honoraria | No conflict of interest to disclose |
| Travel support | No conflict of interest to disclose |
| Other | No conflict of interest to disclose |

Presentation includes discussion of the following off-label use of a drug or medical device: N/A

PROLOR BIOTECH

# PROLOR BIOTECH

*Generation of biobetter drugs by enhancing the longevity of proteins, peptides and small molecules which require frequent injections*

# CTP Technology Created By Nature During Evolution

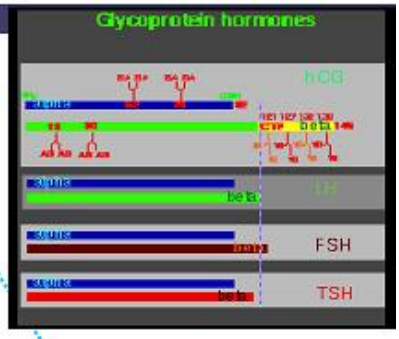
A — Two fertility hormones

B — hCG – maintains pregnancy and requires long T1/2

C — hLH – stimulates ovulation on a pulse mode requiring a short T1/2

D — Amino acid sequence of hCG & hLH is almost identical

E — The 28 amino acid C-terminal peptide (CTP) of hCG with its 4 O-glycans does not exist in hLH




T1/2 of hCG is >5 times longer than T1/2 of LH

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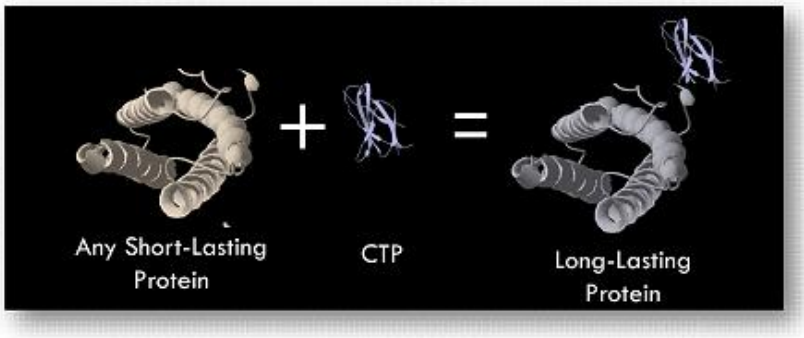
# CTP Increases Proteins Circulation Time

CTP – A Natural Sequence Created During Evolution to Enhance Longevity of the hCG Hormone



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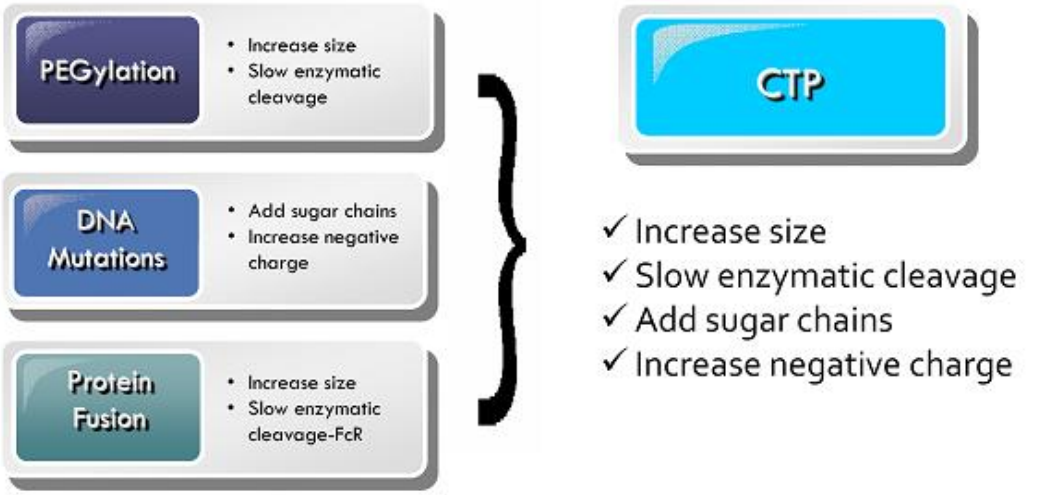
# CTP Competitive Advantages- Best Of Breed Combination



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# CTP: Clinically Validated Technology

- Merck 's long-acting FSH-CTP (Elonva®) received EU marketing authorization in 2010
  - Single FSH-CTP injection replaces 7 daily FSH injections in fertility treatment
  - Extended immunogenicity studies

- PROLOR completed 4 clinical studies with its long acting hGH –CTP, further demonstrating that CTP technology is safe, effective and non-immunogenic.



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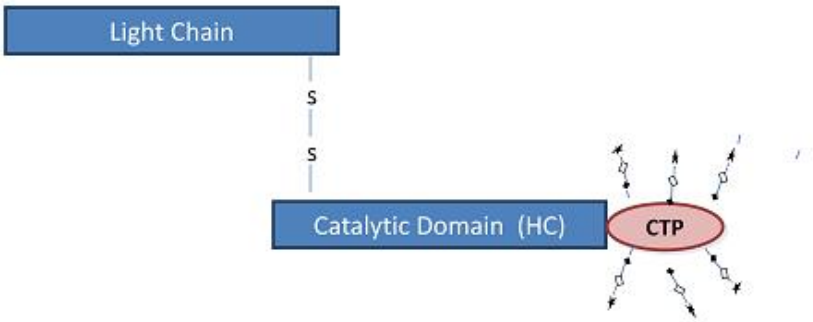
# FVIIa-CTP (MOD-5014)
# Product Description




- FVII-CTP is a single chain FVII directly linked to CTP peptide .
- The protein is expressed in CHO cells
- A FVIIa-CTP (MOD-5014) specific purification and activation process was developed .



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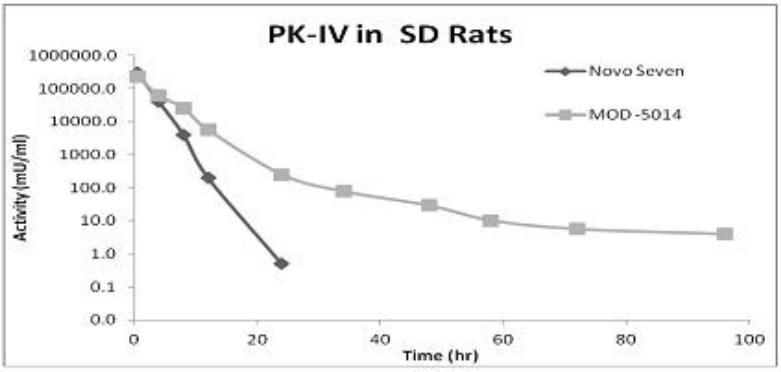
## Long Acting FVIIa-CTP –IV Administration

- **PK-PD rats**
- **Warfarin induced bleeding in rats**
  - Prothrombin time (PT)
  - Bleeding Challenge
- **Hemophilic Mice**
  - PK-PD
  - TG
  - Survival Study

# FVIIa-CTP ( MOD-5014) PK-PD Profile Following a Single IV Injection (189µg/Kg)




| PK Parameters | NovoSeven® | MOD-5014 |
|---|---|---|
| Half-life | 1.31 | 6.49 |
| AUC (U*hr/ml) | 850.423 | 2551.7 |
| MRT (hr) | 1.2 | 3.3 |



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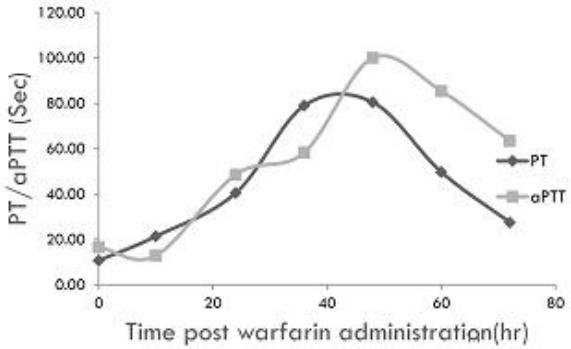
# Warfarin Model-FVII Transient Deficiency

- Male SD rats received Warfarin 24 hours pretreatment (orally) according to *Diness et al. 1990*.
- Reduction of Vit. K dependent coagulation factors was accompanied by prolongation of PT and aPTT was measured .




| Time | PT | aPTT |
|---|---|---|
| 0 | 10.71 | 16.54 |
| 10 | 21.37 | 12.90 |
| 24 | 40.48 | 48.60 |
| 36 | 79.05 | 58.35 |
| 48 | 80.50 | 100.10 |
| 60 | 49.75 | 85.48 |
| 72 | 27.50 | 63.50 |

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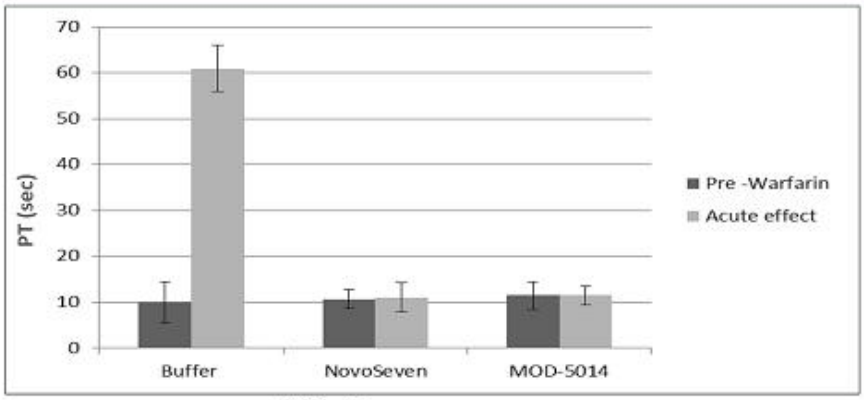
# Warfarin Model-Acute Effect (PT)







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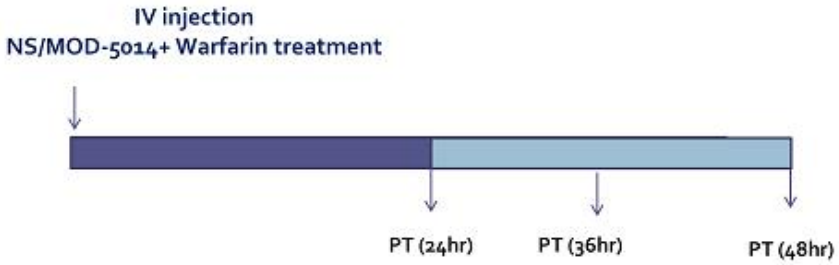
# Warfarin Model- Long Term Effect

- SD Rats were given Warfarin orally
- In- parallel to Warfarin, Novo Seven or MOD-5014 were administered.
- PT was measured at designated time points and compared to placebo post treatment .

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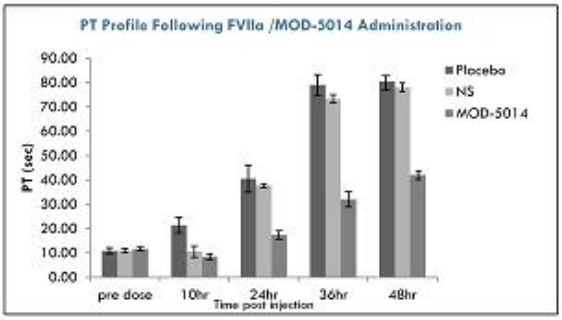
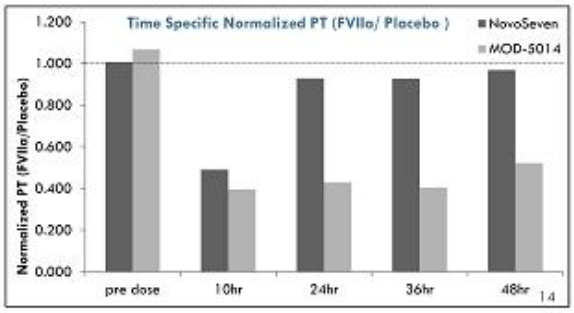
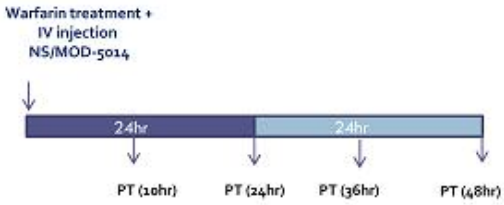
# Warfarin Model-
# Long Term Effect (PT)- 1000µg/Kg




| | Placebo | NS | MOD-5014 |
|---|---|---|---|
| pre dose | 10.87 | 10.93 | 11.60 |
| 10hr | 21.37 | 10.50 | 8.45 |
| 24hr | 40.48 | 37.60 | 17.37 |
| 36hr | 79.05 | 73.30 | 32.00 |
| 48hr | 80.5 | 78.00 | 42.00 |

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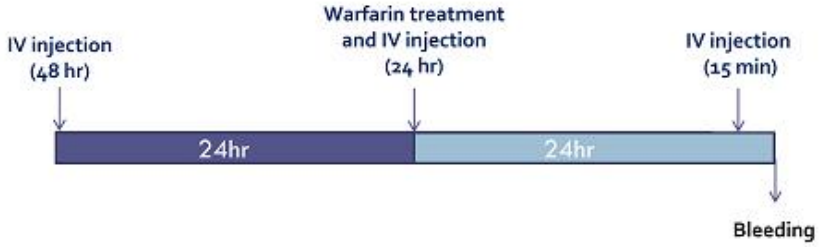
# Warfarin Induced Bleeding Model- Long Term Effect (Tail Clip Model)

- SD Rats were given Warfarin orally
- Rats were anaesthetized and Novo Seven or MOD-5014 were administered in- parallel to Warfarin (1000µg/Kg)
- Full transection of the tail tip was made and bleeding intensity was measured for 30min (gr )

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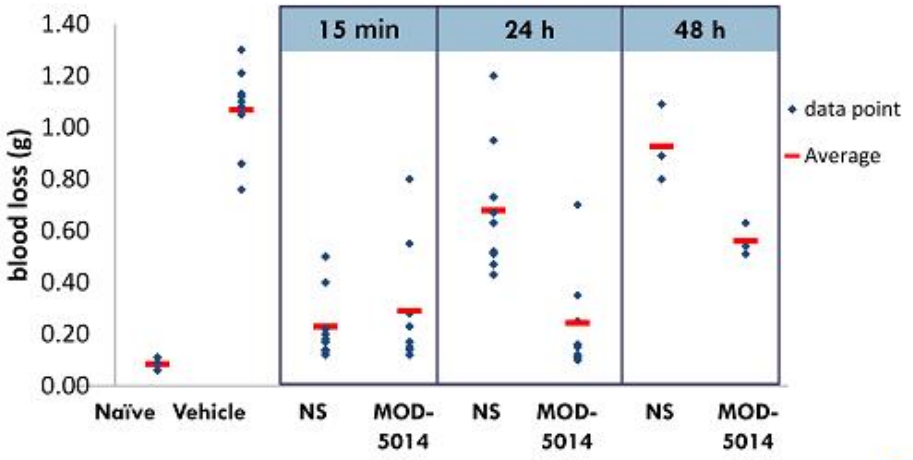
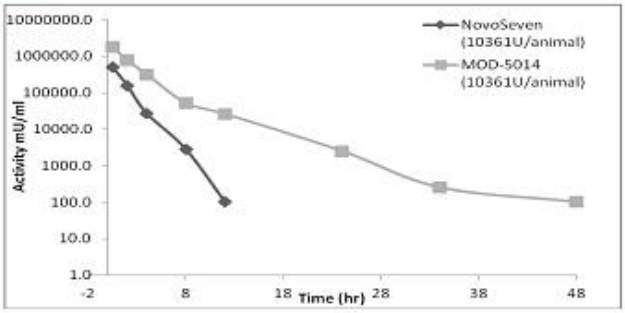
# Warfarin Induced Bleeding Model- Long Term Effect - IV (Tail Clip Model)

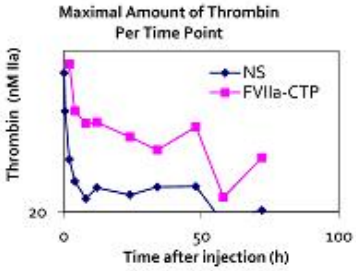


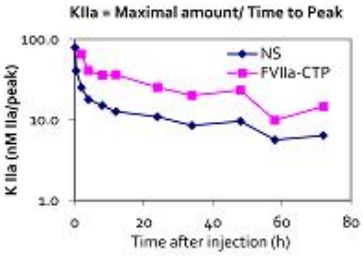
# MOD-5014 PK-PD Profile Following a Single IV Injection to FVIII-/- Mice




| PK Parameters | NovoSeven | MOD-5014 |
|---|---|---|
| Half-life | 0.96 | 5.1 |
| AUC (U*hr/ml) | 103.08 | 496 |
| Recovery | 12.1% | 39% |

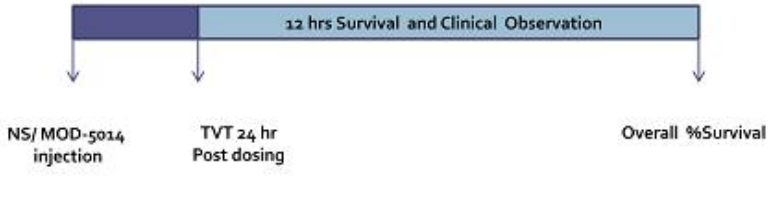
## Thrombin Generation Profile



# TVT (Tail Vein Transection ) Study design

- FVIII -/- mice were administered IV with 4mg FVIIa/Kg of NS or MOD-5014.
- 24 hr post dosing the tail vein was cut .
- Animals survival and clinical condition was evaluated for the next 12 hr.

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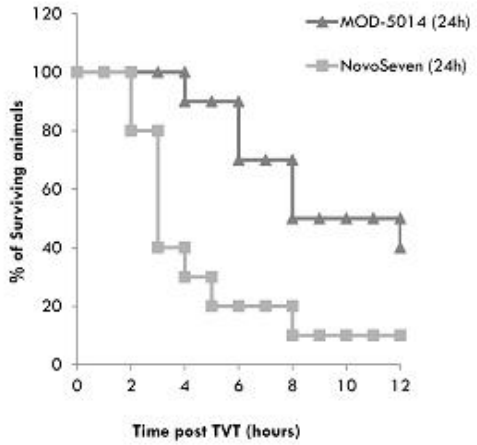
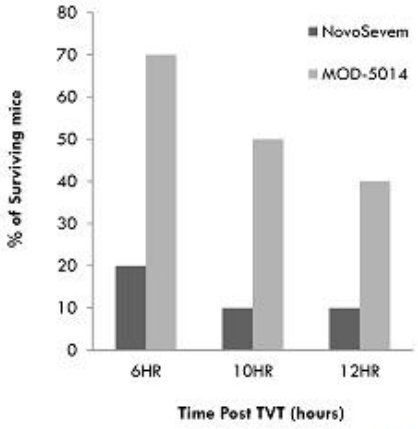
# TVT Study Results – 24hr post injection

## Overall % Survival –TVT 24hr post Injection

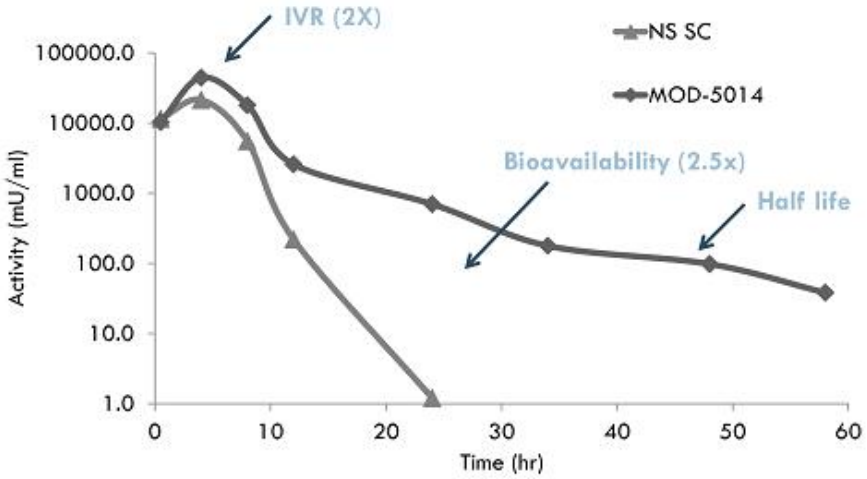




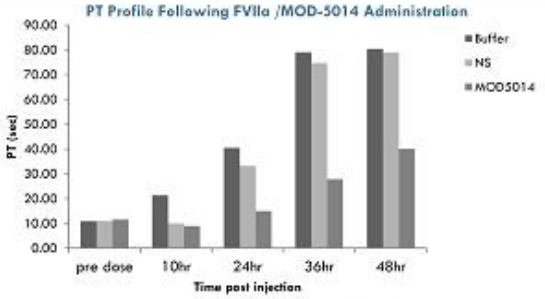

PROLOR BIOTECH

# MOD-5014 PK-PD Profile Following Single SC Injection to Rats (360µg/Kg)

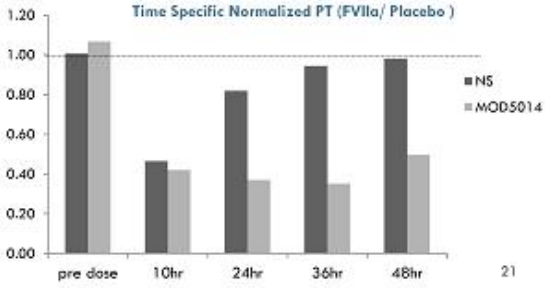


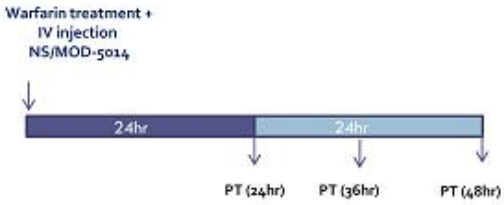

PROLOR BIOTECH

# Warfarin Model-
# Long Term Effect (PT)-SC 2000µg/Kg




| | Buffer | NS | MOD5014 |
|---|---|---|---|
| pre dose | 10.87 | 10.93 | 11.60 |
| 10hr | 21.37 | 9.93 | 8.97 |
| 24hr | 40.48 | 33.17 | 15.00 |
| 36hr | 79.05 | 74.70 | 27.83 |
| 48hr | 80.5 | 79.00 | 40.07 |



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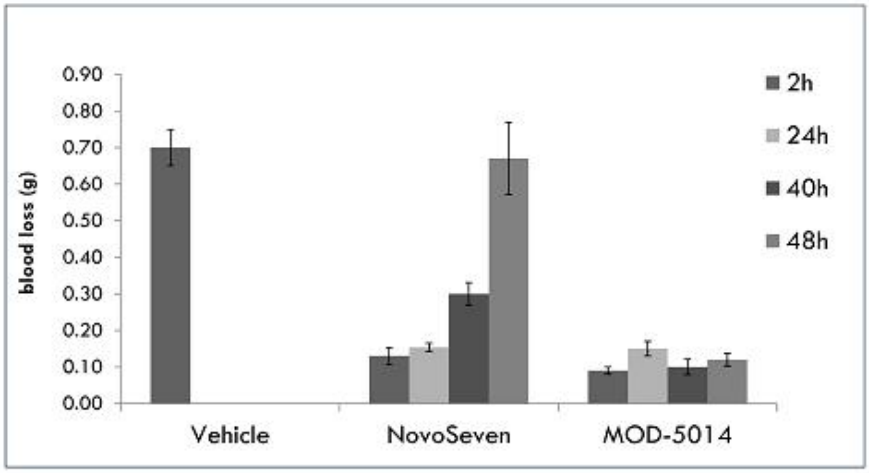
# Warfarin Induced Bleeding Model- Long Term Effect (Tail Clip Model) –SC 1000µg/Kg



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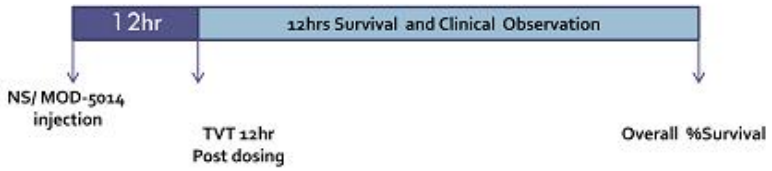
# TVT Following SC Administration Study Design

- FVIII -/- mice were administered SC with MOD-5014 or NovoSeven (4mg/Kg)
- Five mice were injected with 100ul of vehicle as control
- 12hr post dosing the tail vein was cut
- Animals survival and clinical condition was evaluated for the next 12 hr.

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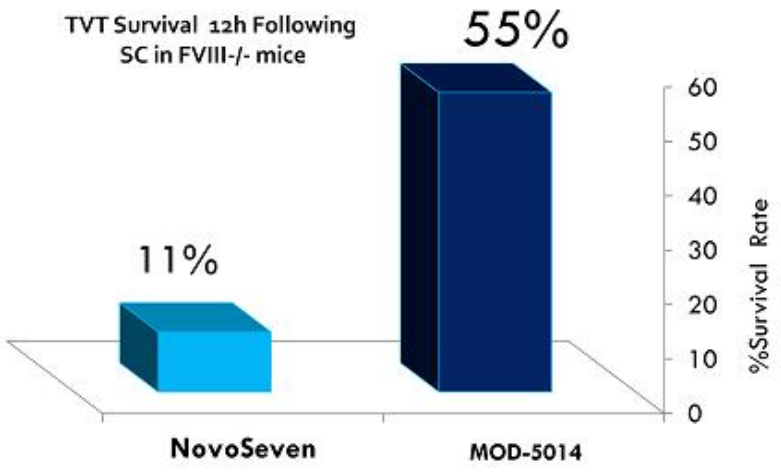
# FVIIa-CTP has a Profound Survival Effect as Compared to NovoSeven following SC Administration





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# MOD-5014 Program-IV Administration : Summary & Perspectives

- **Protein In –vitro Characterization**
  - Similar in- vitro Thrombin Generation (TG) performance as compared to NovoSeven
  - Similar in- vitro coagulation efficiency compared to NovoSeven as evaluated in Thrombelastography (TEG)
  - MOD-5014 specific activity is comparable to NovoSeven
- **Pharmacokinetics Advantages:**
  - Enhanced Recovery (2X)
  - Superior half life (4-5x)
  - Improved exposure (AUC3- 4x)
  - Improved Thrombin Generation
- **Long term and Superior In –Vivo Haemostatic effect**
  - PT in Rats
  - Bleeding challenge in rats
  - Ex-Vivo Thrombin Generation (TG) in hemophilic mice
  - Improves survival maintained for more than 24 hrs following TVT .

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# MOD-5014 Program Status

- **Manufacturing**
  - ✓ Manufacturing process performance is comparable to NovoSeven
  - ✓ large scale GMP manufacturing process
  - ✓ High concentration Liquid formulation (Supports SC)
  - ✓ Non –Viscous
- **Pre-Clinical**
  - ✓ Pharmacological studies –completed
  - ✓ Toxicological program-On going
- **Clinical**
  - ✓ Phase I-IIa (IV indication )-in preparation
  - ✓ Phase I (SC indication)- in preparation

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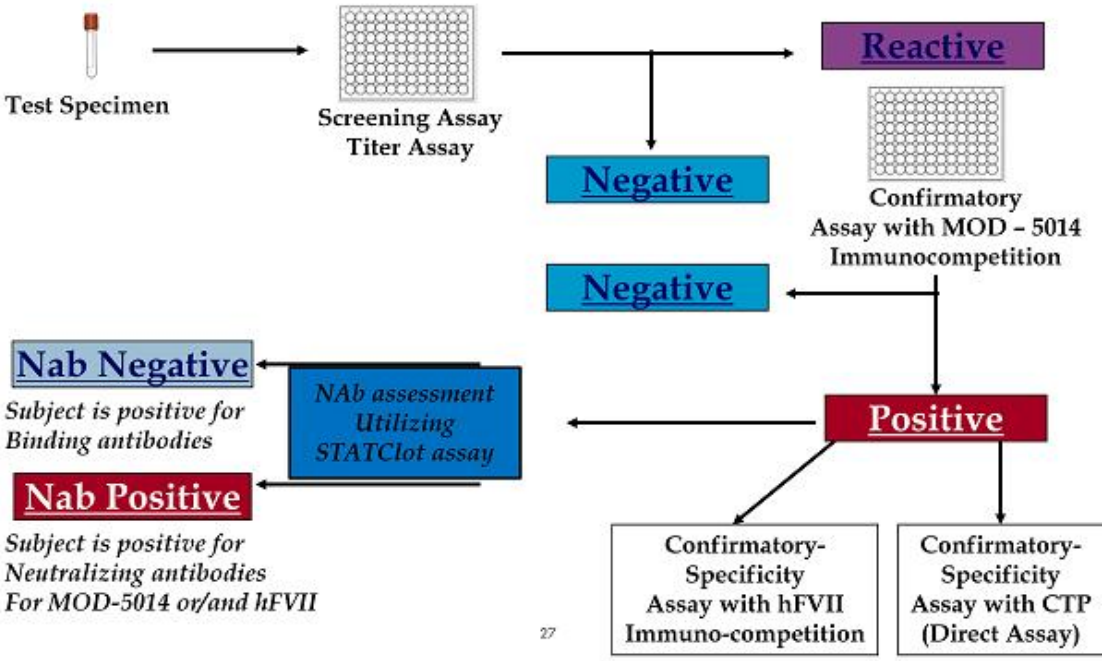
# Immunogenicity Testing



# Thank You

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