

KINLYTIC®

Non-Confidential Information
Presentation

Nov 2019 long version



Returning Kinlytic® urokinase to the US market for Catheter Clearance

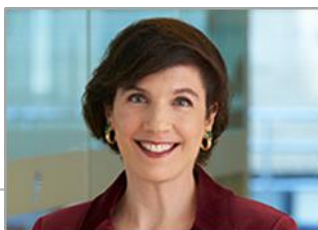


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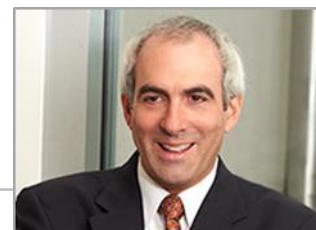


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Urokinase for catheter clearance – The Lead Opportunity

- Kinlytic® urokinase, formerly Abbokinase® – approved for multiple indications in North America
- **Lead opportunity - return of Kinlytic® for catheter clearance (CC) in the US market**
 - Catheter clearance is return of flow to a central venous catheter (CVC) clogged with a blood clot
- US catheter clearance is a monopoly market, growing 8-10% annually to \$330mm* in 2018
- **2018 market research confirms need for catheter clearance thrombolytic competition**
 - No new market entrant for 15 years - respondents seek improved price competition, better product convenience, reliable outcomes
 - Kinlytic® was gold standard for CC - no molecule risk - established record of safety, efficacy
 - Discount to incumbent pricing a driver for sales growth
 - Low manufacturing risk and costs, using CMOs
- **FDA response positive on plan for return to US market**
- **Annual sales of \$250mm expected for first indication, in the USA only**
- **Project IRR >80%**
- **\$18mm investment to sNDA filing in 2½ years**
 - Other well-understood clinical indications offer follow-on opportunities

Kinlytic® Urokinase Overview

Overview

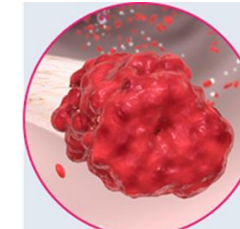
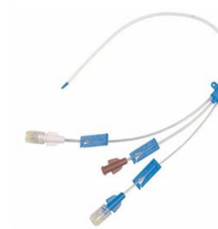
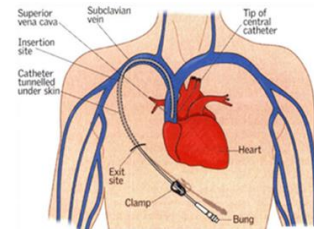
- **Kinlytic® (low molecular weight urokinase, LMW-UK), the only approved LMW-UK worldwide**
- Initially approved in 1978 as Abbokinase – Abbott achieved peak sales of \$274mm in 1998 - 50% of thrombolytic market
- Microbix owns all rights – approved NDA, validated cell banks, critical reference materials, trade secrets
- **Targeting the fastest growing, lowest risk and highest return indication – catheter clearance (CC)**

Indication

- **Approved indications in the US and Canada include:**
 - Restoration of patency to intravenous catheters obstructed by clotted blood or fibrin (5,000 IU/unit) – Catheter clearance (CC)
 - Lysis of acute massive pulmonary emboli (250,000 IU/unit)

Catheter Clearance

- Central venous catheters (CVCs) are used to access patient's vasculature/circulation for: oncology, infection, nutrition, dialysis
- CVC use growing rapidly but 25% of catheter will clog with blood cots
- Only other drug approved for catheter clearance is Cathflo Activase®
- **Return of Kinlytic urokinase will result in a long term duopoly**



Re-Launch Plan

- Microbix has extensive experience with the cell-culturing methods used to produce LMW urokinase
- **FDA has reviewed its detailed plan to file sNDA to return Kinlytic for catheter clearance**
- **Budget validated by 3rd party CMO quotations the re-launch process - \$18mm, 2 years to FDA filing**

Financial Projection

- **Catheter clearance sales estimated at \$183mm by yr 5 in market**
- **>70% fully-loaded margin after manufacturing, selling and distribution**
- **Sales of \$257mm by yr 10 in market - US only, one indication only**

A 3D ribbon diagram of a protein structure, likely Kinlytic, rendered in various colors (blue, red, yellow, green) to highlight different regions or domains. It is positioned in the upper left corner of the slide.

Kinlytic® Product Differentiation/Market Strategy

- 2018 independent market research sponsored by Microbix
 - Confirmed that the US CC market wants an alternative to Cathflo Activase®
 - Confirmed Kinlytic® has properties that will enable it to take market share from Cathflo Activase®
- Enables positioning Urokinase for gain of share based upon:
 - Substantial price discount to t-PA
 - Equal efficacy to t-PA
 - Equal or better safety profile as t-PA
 - Dosage format to provide greater convenience & ease of use, minimizing risks of errors and contamination
 - Storage at room temperature on patient floor, with longer stability (18 months RT vs t-PA 12 months refrigerated)
 - t-PA needs cold storage at 4°C off the patient floor in pharmacy
 - Predictable CC outcomes
- Kinlytic also provides an alternate source of thrombolytic, helping avoid disruption of drug supply
 - Disruptions to US supply of t-PA have occurred

Kinlytic® Market Differentiation – Dosage Form Advantages

Kinlytic – convenience on the patient floor

Kit with UK
vial and WFI
syringe



or

Single
syringe with
UK and WFI



Versus

Cathflo – off in the pharmacy refrigerator



*Plus sterile WFI vial,
syringe, transfer set*

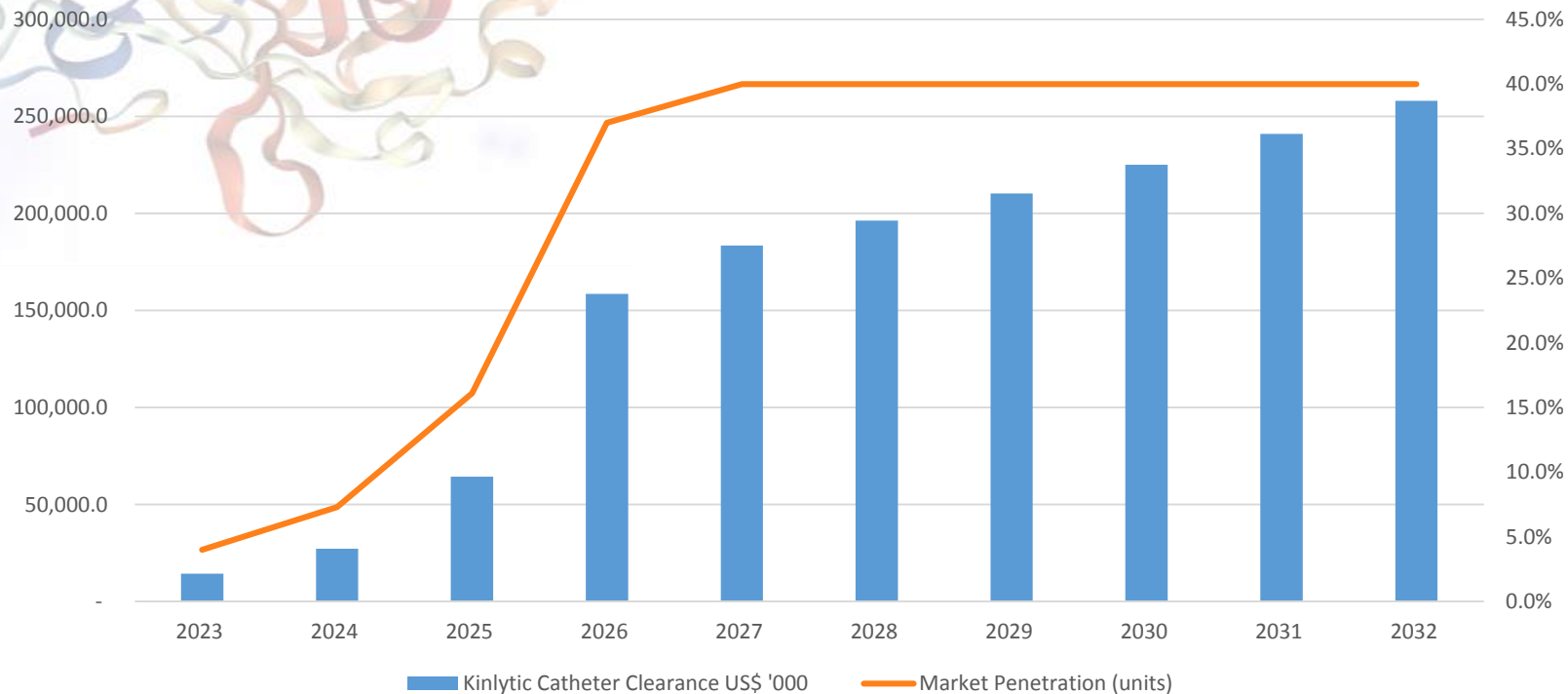


Independent Research into Needs of CC Market in the USA

- Two US market studies were executed by two independent research firms to determine the needs, wants and motivators of hospital / clinic decision makers and influencers responsible for catheter clearance
 - Determined key issues for success of urokinase as competitor to Cathflo Activase®
 - Studies were completed in 2007 and 2018
 - Contemporary study intended to confirm/enhance earlier support for urokinase product
- Overall Bottom-line findings from respondent feedback:
 - Desire for a 2nd thrombolytic providing equal or better efficacy, safety and reduced costs
 - 2nd product should be easy to use, work quickly and have excellent sales support
 - The Kinlytic® urokinase mode of action is well-understood
 - The proposed dosage form is attractive, offering material advantages
 - Respondents believed Kinlytic can meet their wants
 - Clinical practise for treatment of occluded catheters has not changed in the last decade

US Market – Desire for Thrombolytic Competition Helps Drive Growth

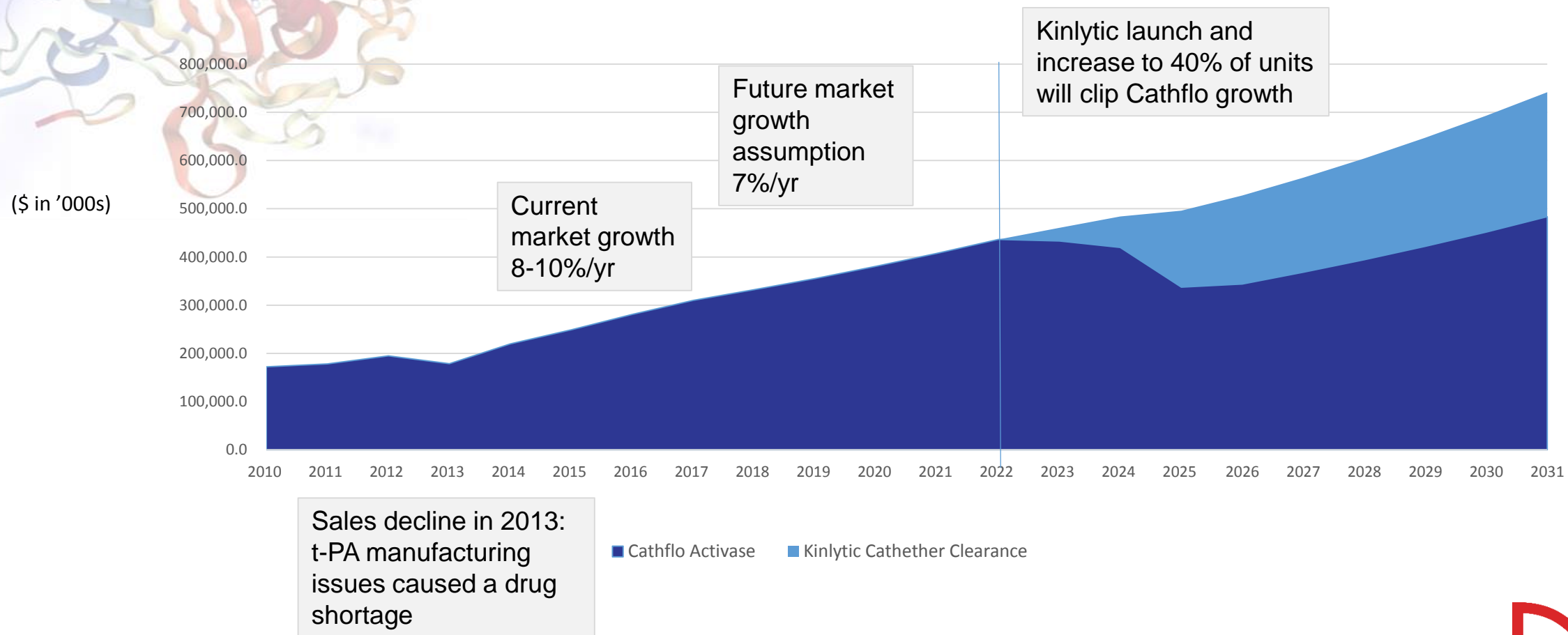
Projected Kinlytic Catheter Clearance Sales Growth and Units Penetration



Kinlytic penetration and sales growth fueled by:

- Discount to Cathflo then pricing in lock-step
- Known safety and efficacy – equal or better than t-PA
- Predictable outcomes
- Superior dosage format for advantage in convenience and reduction of dosing errors and contamination
- Advantageous storage:
 - Room temperature on patient floor instead of pharmacy refrigerator
 - Longer expiration

US Catheter Clearance – A Market with Two Players



Target Segmentation Focus with Timelines

**Focus on
Historical Top 10
– 20 Accounts**



**Expand Focus to
Next Tier of
Historical Top
Accounts**



**Expand Focus to
Next Tier of
Historical Top
Accounts not yet
Penetrated**



**Expand Focus to
Newer Accounts
for More Breadth
of Business – Rely
on Reps Feedback**



First 6 Months

Next 6-12 Months

Next 12 Months

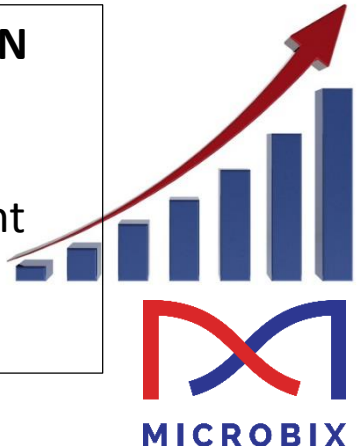
30 Months+



**Nursing – 50% Call Point
Physicians – 25% Call Point
Administrators – 25% Call Point
*5-6 FTE Reps, Strong Closers!,
Compensate Well**



***Adjust Call Point Percentages PRN
Nursing – 30-40% Call Point
Physicians – 25- 35% Call Point
Administrators – 25- 35% Call Point
*6-8 FTE Reps, Strong Closers!,
Compensate Well**



Barriers to Competition from Biosimilar Thrombolytics

Thrombolytic market has high barriers to potential competition

Different from the monoclonal antibody market for oncology

- USA Biosimilar Regulations require significant cost and effort in analytical, preclinical and clinical studies
 - Few approvals in half a decade – most are antibodies – no thrombolytics, including t-PA
 - No biosimilar LMW-urokinase or t-PA products have been approved in any more permissive region, such as Europe or even China and India
- Significant technical hurdles to production of a LMW-UK biosimilar
 - Is a two chain glycoprotein and, like t-PA, has complex post-translational secondary and tertiary structure
 - Urokinase in particular is difficult to manufacture by recombinant means
 - Urokinase protected by closely held trade secrets - Abbott patents expired 1993 – still no competition
 - Analytical comparability is confounded by Kinlytic® excipients – known firsthand from Microbix' prior experience with FDA on its biosimilar urokinase effort
- **Microbix believes that development of a biosimilar version of Kinlytic® will not begin until it has been re-established in the market, thus the earliest possible biosimilar approval is 7-10 years away, if ever**

Kinlytic® for Catheter Clearance – Project Economics

- Microbix' lead opportunity for Kinlytic® is re-launch for catheter clearance
 - Plan requires only \$18 million and 29 months to sNDA submission
 - All costs and timelines validated by 3rd parties
 - Single required bridging trial is quick and inexpensive, needing just 6 months and costing only \$1.7 million
 - Clear regulatory path: FDA provided input into Microbix' plan, confirming that it is a reasonable pathway for re-entering the US market
- Microbix believes the Catheter Clearance indication is rewarding on its own – other indications are a bonus
 - Cumulative 10 year CC sales of ~\$1.4 billion
 - Projected CC product fully-burdened margin of >70%, based upon using contract manufacturers
 - IRR in excess of 80% for CC indication in US-only
 - Modeling CC sales in year 5 in market of \$183 million and year 10 of \$257 million
 - Ongoing CC segment sales growth of $\geq 7\%$ per year
- Catheter Clearance market likely to be a duopoly for the long term
- Franchise growth opportunities are available through expansion into other clinical indications

Kinlytic re-launch to follow a well-developed regulatory pathway

Kinlytic is already approved - the steps to return to the US market include

- Implement manufacturing and testing upgrades as discussed with FDA
- Install the process in manufacturing facilities and prepare drug substance and drug product
- Perform comparability as discussed with FDA
- File a supplement to the approved NDA (sNDA)
- FDA agreed that “**Microbix plan, as modified by FDA input, is a reasonable path forward for urokinase for catheter clearance return to market**”
 - Regulatory risk is therefore both low and well-understood

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2. QUESTIONS AND RESPONSES

2.1. Chemistry, Manufacturing and Controls

Question 1:

Microbix will manufacture new batches of urokinase drug substance by replicating as much as feasible the urokinase manufacturing process as described in NDA 21-846. Replicating the original process will require updating parts of the old process with modern options. The objective of the updates is to use modern methodologies for improved process control, reduce the use of animal derived raw materials, and reduce process related impurities. Does FDA have comments about this approach to updating the drug substance manufacturing process?

FDA Response to Question 1:

Your proposal to update the drug substance manufacturing process appears reasonable. Note that the adequacy and approvability of the updated manufacturing process and the associated control strategy will be during review of your submission and inspection of the manufacturing facility. In addition, please refer to our responses to Question 2 and Question 4 (1) below.

Reference ID: 4088821



Catheter Clearance: Comparability for Re-launch

Clinical Comparability: **Only requirement** is quick and low-risk bridging study

- Cost of bridging study is \$1.7 million and will take only 6 months to complete
- High catheter occlusion rates mean rapid enrollment and efficacy endpoint in minutes
Efficacy is determined by assessing flow in the catheter after 1 or 2 treatments
Treatment is 5000 IU of LMW-UK for up to 90 minutes in the blocked catheter
- Design is a randomized, double-blind, placebo-controlled multicenter (40 sites) study in 324 patients with occluded CVADs, with efficacy and safety endpoints

Analytical and non-clinical comparability:

- Microbix's frozen reference and World Health Organization LMW-UK reference to be comparators to newly-produced product
- Analytical testing to be supported by clinical data
- Repeat Abbott's rabbit and dog pharmacokinetics studies



Contract Strategy for Manufacturing, Testing and Development

- Microbix developed its project timeline and budget to market launch based on third party independent input on all aspects of project completion
- Quotes were obtained from qualified and experienced contract manufacturing (CMOs) and contract research organizations (CROs) about completion of project elements, including
 - Drug Substance manufacture, Drug Product manufacture, Test method development, Cell bank testing, Batch safety testing, Validation, Characterization and analytical comparability, Nonclinical studies (Animal PK), Clinical bridging study, Sales and Marketing costs for market launch pre and post sNDA approval
- Plan envisions a team involving or supported by Microbix to “bolt-on” to a partner in order to execute the project
 - It is understood that a partner may want either more or less direct involvement in the project
- **Result of quoted input from vendors:**
 - **2½ year timeline to filing of the supplement (sNDA) followed by FDA review**
 - **\$18mm project budget over the 2+ years**

Catheter Clearance: Budget to sNDA Filing

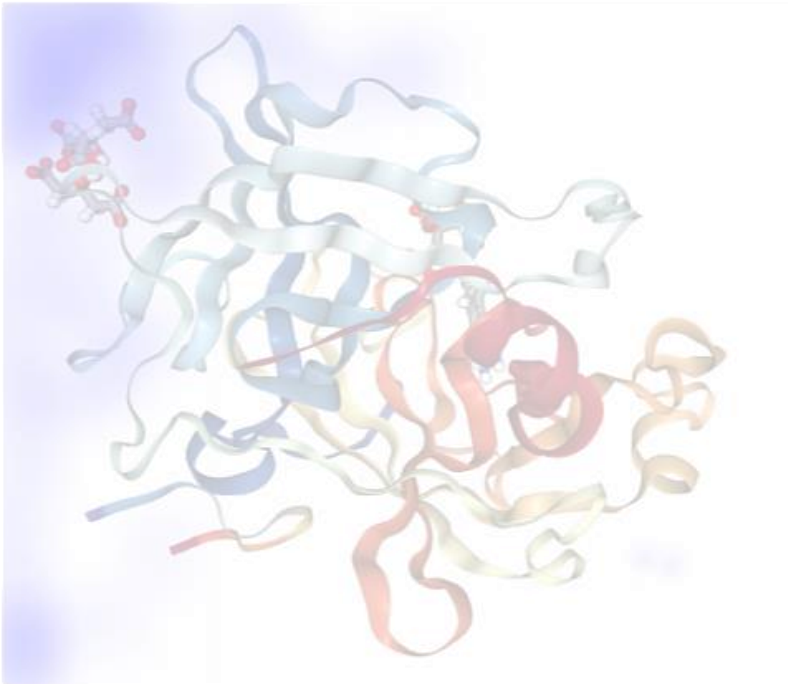
- Budget is constructed based on use of third-party service providers
- All such service providers quoted to meet the project timeline to sNDA filing

Drug substance manufacturer	\$5.6
Cell bank / infectious disease batch testing	\$1.6
Viral clearance validation	\$0.3
Test development / characterization CRO	\$1.3
Drug product manufacturer	\$3.1
Non-clinical studies	\$0.2
Clinical trial	\$1.7
Project team (development/finance/commercial and ex-Abbott and Microbix transfer)	\$3.4
FDA fees	\$1.0
<u>Total expenses to sNDA filing</u>	<u>\$18.2</u>

Capital (Drug Substance CMO equipment and renovation \$2.3, Drug Product CMO for dedicated equipment \$0.3)	\$2.6
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Path to re-enter US market is believed to be de-risked and rapid

- ✓ No molecule risk, as LMW-UK is approved and has well-proven outcomes in clinical practice
- ✓ Regulatory risk is minimized, as FDA appears satisfied with clinical and non-clinical plans
 - ✓ *Cell banks* ✓ *Process modernizing* ✓ *Raw materials* ✓ *Testing* ✓ *One bridging study*
- ✓ Manufacturing risk is small, with production via qualified CMOs or by Microbix/Partner
 - ✓ Urokinase is produced from a stable & reliable cell line. Reviewed with the FDA in 2017.
- ✓ Market risk is low, with a clear (>\$300 million) and growing (8-10%) lead indication
 - ✓ 2018 direct to user / decision maker market research has confirmed the need for Kinlytic competition to the incumbent
- ✓ Financial commitment to approval is just \$20 million, all validated via 3rd party quotes
- ✓ Timing is only two years to sNDA filing
- ✓ Multiple barriers for any other entrant into US market for CC
 - Both t-PA and LMW-UK have molecular and formulation complexity barriers to biosimilars
- ✓ Further growth driven by other indications and territories



Appendix 1

Expansion of Kinlytic[®] Catheter Vial Indications: Prophylaxis of Catheter Related Complications

Follow-on Indication: Prophylaxis of Catheter-related Complications

Extension to the use of the 5000 IU/mL catheter clearance product – clinical evidence is available

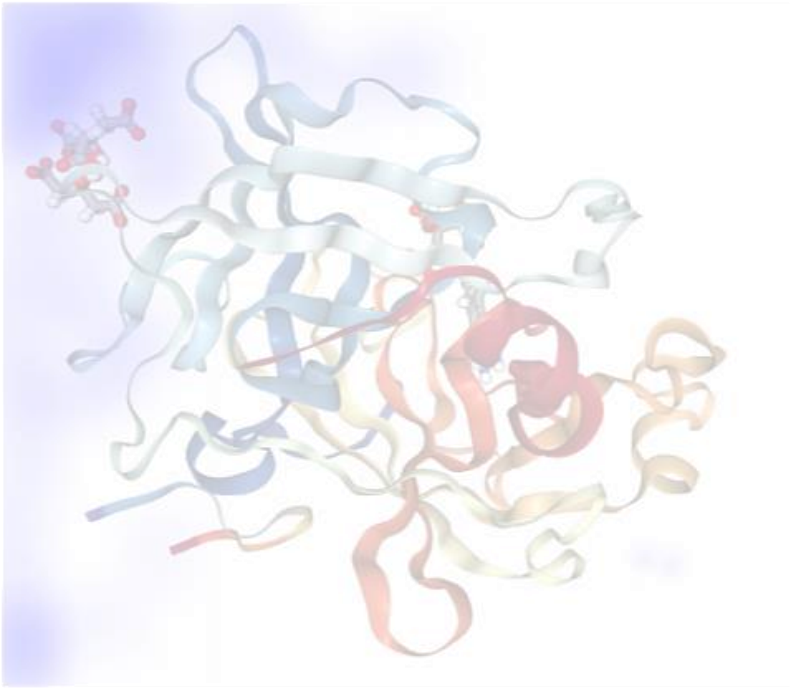
- **“Catheter Prophylaxis” - a bi-weekly catheter treatment to reduce catheter-related complications**
 - Catheter use can lead to serious clinical complications
 - Catheter-Related Blood-Stream Infections (CRBSI) – >200,000 patients/year (US)¹
 - Catheter Related Thrombosis (CRT) – 1.8mm patients, at least once/year (US)
 - Trial data
 - Urokinase prophylaxis decreased the incidence of catheter occlusions from 68% in the control group to 23% in the treatment group; in some studies, rates of catheter infections were also decreased in the urokinase group²
 - Urokinase prophylaxis trial in 2004 showed statistically significant reduction and delay of catheter-related blood-stream infections and catheter-related thrombosis in pediatric oncology patients³
 - Potential savings to US health care system \$2.5-3.5 billion/year ⁴
 - Clinical trial is needed to build on previous work to expand Kinlytic indication
 - Projected to increase Kinlytic sales for catheter management to \$450mm/year (combined catheter clearance indication plus prophylaxis)

1. Implementing evidence-based practices to reduce catheter-related bloodstream infections in the intensive care unit." American Journal of Infection Control 33.5 (2005): e61-e62;

2. Thrombolytic therapy for central venous catheter occlusion, Haematologica. 2012 May; 97(5): 641–650;

3. Prophylactic urokinase in the management of long-term venous access devices in children, Journal of Clinical Oncology. 2004 Jul 1; ;22(13):2718-23

4. Bokento Consulting 2007, Urokinase Prophylaxis of catheter related complications

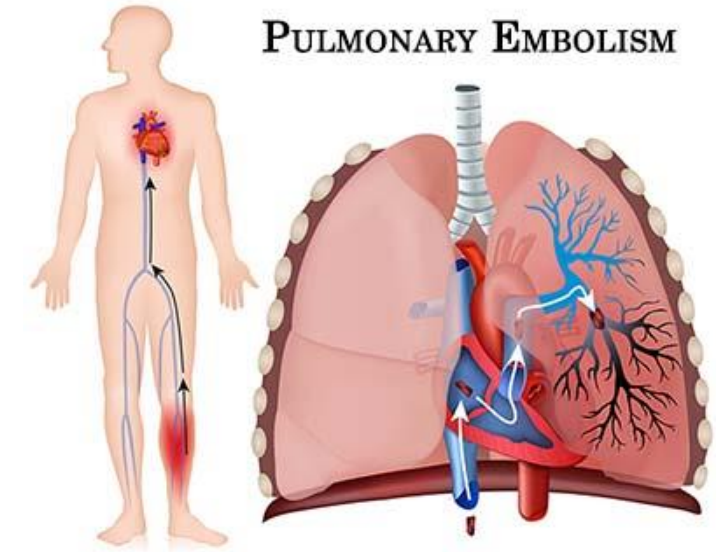


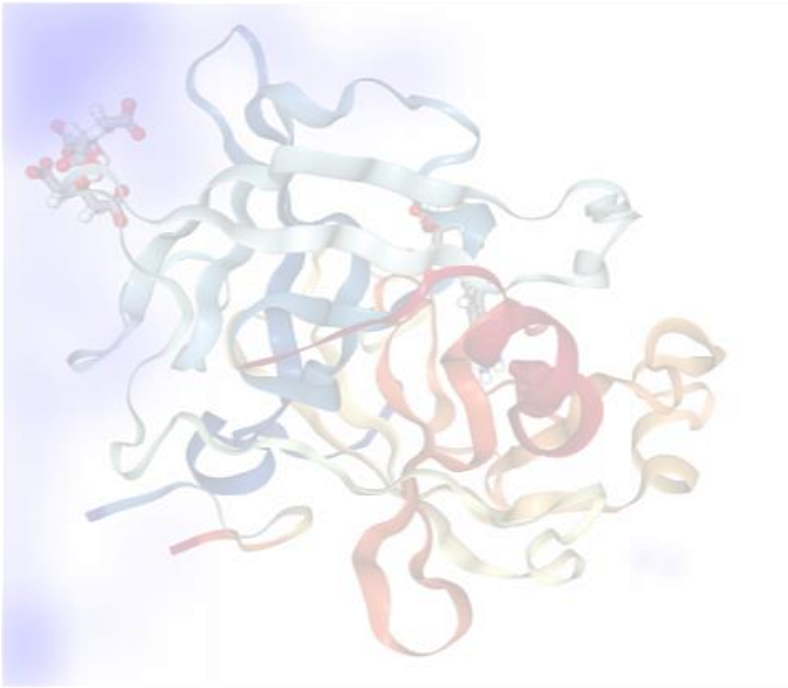
Appendix 2

Kinlytic[®] for approved PE Indication

Another Approved Indication to Relaunch: Pulmonary Embolism¹

- Kinlytic is currently FDA-approved for Pulmonary Embolism (PE)
- Clinicians have lamented the loss of urokinase; a thrombolytic agent that had become the standard of care for many indications, including PE
- Clinical data indicates the risk of bleeding for peripheral clot treatments is higher with t-PA than urokinase
 - t-PA is fibrin activated so it acts on all clots - problem in-vessel clots and normal body-repairing hemostatic clots
 - Urokinase does not rely on fibrin for its activity and has a short half-life and therefore does not target normal hemostatic clots
 - Therefore, urokinase is less prone to cause uncontrolled, systemic bleeding
 - Urokinase is a safer alternative to t-PA for peripheral indications such as PE
- Laboratory evidence suggests that urokinase is associated with advantageous compromise between speed of thrombolysis and fibrinolytic specificity
- Approximately \$90mm thrombolytic US Market for PE (2017)
- At 50% market share, possible US Kinlytic[®] sales for PE = \$45mm/year



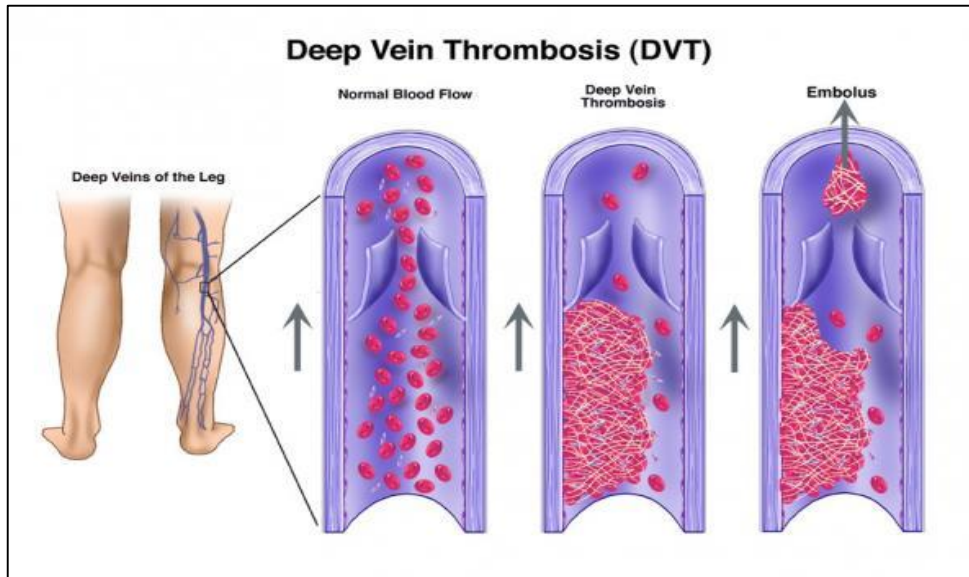


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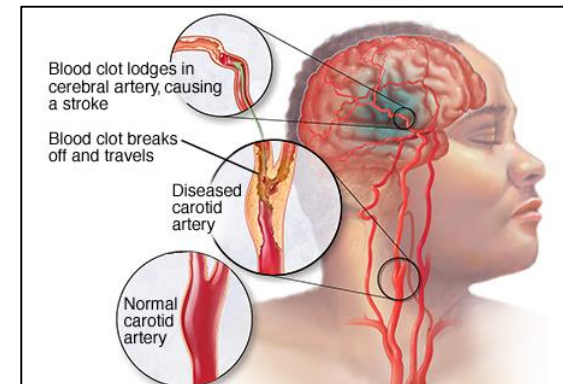
Expansion of Kinlytic[®] Indications for Peripheral Clot Treatments

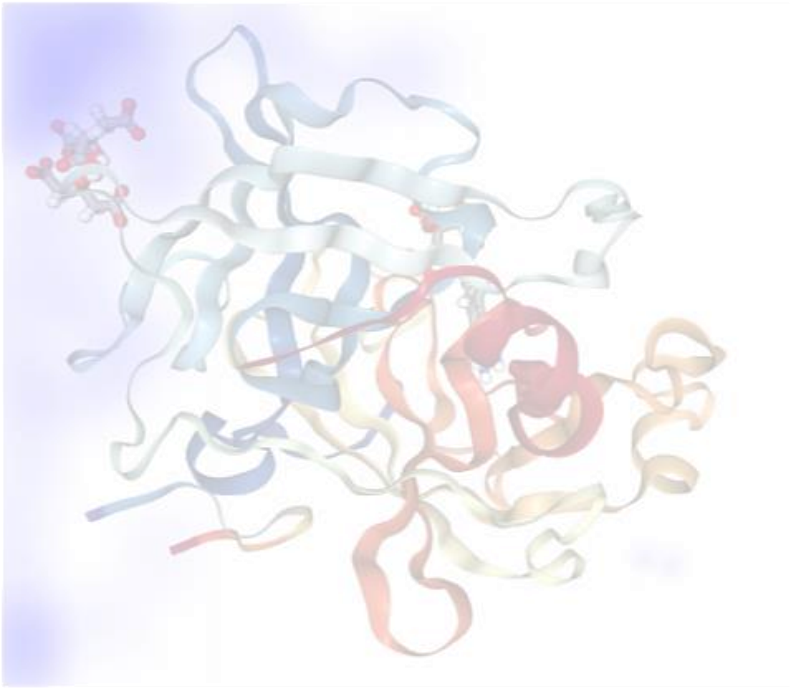
Historical Off-label Uses Suggest Indication Expansion Opportunities

- **Peripheral Market Potential (DVT, PAO, PVD)**
 - Total Lytic Sales in Peripheral Market in 2017 dollars = \$757mm¹
 - Projected possible Kinlytic® US Peripheral Market sales = \$227mm/year (@ 30% market share)
 - Safer for longer infusions in large vessels than t-PA because does not impact hemostatic clots, so lower hemorrhaging risk, and can be used even if patient on heparin (t-PA has a higher bleed risk with heparin)



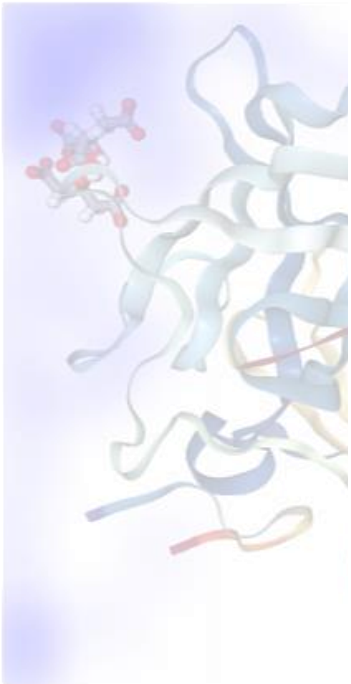
- **Stroke Market Potential¹**
 - Stroke category represents significant unmet medical need
 - 800,000 strokes per year in US; Strokes costs US \$38bn per year; ~650,000 Stroke patients/year qualify for lytic therapy
 - Potential for premium pricing based on superior efficacy & safety (lower hemorrhaging risk)
 - Estimated US stroke market = \$575mm (@ 40% qualified patients receiving lytics)
 - Projected possible Kinlytic® Stroke Sales = \$200mm (@ 35% market share)





Appendix 4

1998 Urokinase for Catheter Clearance Label



ABBOKINASE® OPEN-CATH® R (Urokinase for Catheter Clearance)

DESCRIPTION

Urokinase is an enzyme (protein) produced by the kidney, and found in the urine. There are two forms of urokinase differing in molecular weight but having similar clinical effects. Urokinase is a thrombolytic agent obtained from human kidney cells by tissue culture techniques and is primarily the low molecular weight form. It is supplied as a sterile lyophilized white powder. Following reconstitution ABBOKINASE OPEN-CATH solution is clear and essentially colorless.

Each mL of reconstituted ABBOKINASE OPEN-CATH solution contains 5000 IU of urokinase activity, 5 mg gelatin, 15 mg mannitol, 1.7 mg sodium chloride and 4.6 mg monobasic sodium phosphate anhydrous. The pH is adjusted with sodium hydroxide and/or hydrochloric acid prior to lyophilization.

CLINICAL PHARMACOLOGY

Urokinase acts on the endogenous fibrinolytic system. It converts plasminogen to the enzyme plasmin. Plasmin degrades fibrin clots as well as fibrinogen and other plasma proteins. When used as directed for I.V. catheter clearance, only small amounts of urokinase may reach the circulation; therefore, therapeutic serum levels are not expected to be achieved. Nevertheless, one should be aware of the clinical pharmacology of urokinase. Intravenous infusion of urokinase in doses recommended for lysis of pulmonary embolism is followed by increased fibrinolytic activity. This effect disappears within a few hours after discontinuation, but a decrease in plasma levels of fibrinogen and

plasminogen and an increase in the amount of circulating fibrin (ogen) degradation products may persist for 12–24 hours).^{1,2} There is a lack of correlation between embolus resolution and changes in coagulation and fibrinolytic assay results. Information is incomplete about the pharmacokinetic properties in man. Urokinase administered by intravenous infusion is cleared rapidly by the liver. The serum half-life in man is 20 minutes or less. Patients with impaired liver function (e.g., cirrhosis) would be expected to show a prolongation in half-life. Small fractions of an administered dose are excreted in bile and urine.

INDICATIONS AND USAGE

ABBOKINASE OPEN-CATH (urokinase for catheter clearance) is indicated for the restoration of patency to intravenous catheters, including central venous catheters, obstructed by clotted blood or fibrin.^{3,4,5}

CONTRAINDICATIONS

Because thrombolytic therapy increases the risk of bleeding, urokinase is contraindicated in the following situations:

- Active internal bleeding
- History of cerebrovascular accident
- Recent (within two months) intracranial or intraspinal surgery
- Recent trauma including cardiopulmonary resuscitation
- Intracranial neoplasm, arteriovenous malformation, or aneurysm
- Known bleeding diathesis
- Severe uncontrolled arterial hypertension

There have been no reports, however, which would suggest a contraindication for the use of urokinase for I.V. catheter clearance.

WARNINGS

Excessive pressure should be avoided when ABBOKINASE solution is injected into the catheter. Such force could cause rupture of the catheter or expulsion of the clot into the circulation. During attempts to determine catheter or occlusion, vigorous suction should not be applied due to possible damage to the vascular wall or collapse of soft-wall catheters. Catheters may be occluded by substances other than fibrin clots such as drug precipitates. ABBOKINASE solution is not effective in such cases and there is the possibility that the substances may be forced into the vascular system.

PRECAUTIONS

Carcinogenicity

Adequate data is not available on the long-term potential for Carcinogenicity in animals or humans.

Pregnancy

Pregnancy Category B. Reproduction studies have been performed in mice and rats at doses up to 1,000 times the human therapeutic dose and have revealed no evidence of impaired fertility or harm to the fetus due to urokinase. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when urokinase is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

The following reactions have been associated with ABBOKINASE (urokinase for injection) in doses recommended for lysis of pulmonary embolism.

Bleeding

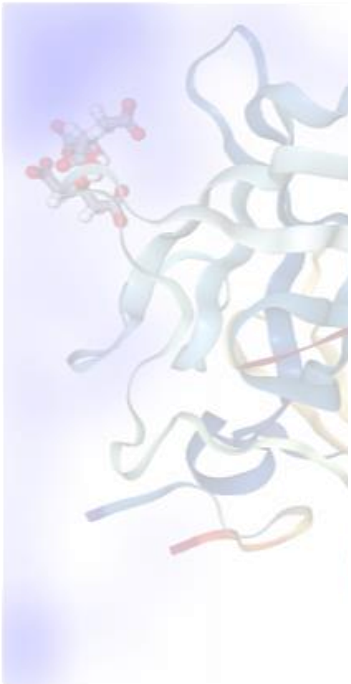
The type of bleeding associated with thrombolytic therapy can be placed into two broad categories:

—Superficial or surface bleeding, observed mainly at invaded or disturbed sites (e.g., venous cutdowns, arterial punctures, sites of recent surgical intervention, etc.).

—Internal bleeding, involving, e.g., the gastrointestinal tract, genitourinary tract, vagina, or intramuscular, retroperitoneal, or intracranial sites. Several fatalities due to intracranial or retroperitoneal hemorrhage have occurred during thrombolytic therapy. Should serious bleeding occur, urokinase infusion should be discontinued and, if necessary, blood loss and reversal of the bleeding tendency can be effectively managed with whole blood (fresh blood preferable), packed red blood cells and cryoprecipitate or plasma. Dextran and hetastarch should not be used. Although the use of aminocaproic acid (ACA, AMICAR®) in humans as an antidote for urokinase has not been documented, it may be considered in an emergency situation.

Allergic Reactions

In vitro tests with urokinase, as well as intradermal tests in humans, gave no evidence of induced antibody formation. Relatively mild allergic type reactions, e.g., bronchospasm and skin rash, have been reported. When such reactions occur, they usually respond to conventional therapy. In addition, rare



cases of anaphylaxis have been reported.

Miscellaneous

Fever and chills, including shaking chills (rigors), nausea and/or vomiting, transient hypotension or hypertension, dyspnea, tachycardia, cyanosis, back pain, hypoxemia, and acidosis have been reported together and separately. Rare cases of myocardial infarction have also been reported. A cause and effect relationship has not been established. Aspirin is not recommended for treatment of fever.

DOSAGE AND ADMINISTRATION

BECAUSE ABBOKINASE OPEN-CATH POWDER CONTAINS NO PRESERVATIVE, RECONSTITUTED SOLUTION SHOULD BE USED IMMEDIATELY AFTER RECONSTITUTION. DISCARD ANY UNUSED PORTION.

Preparation of Solution:

Univial:

1. Remove protective cap. Turn plunger-stopper a quarter turn and press to force diluent into lower chamber.
2. Roll and tilt to effect solution. Use only a clear, essentially colorless solution.
3. Sterilize top of stopper with a suitable germicide.
4. Insert needle through the center of stopper until tip is barely visible. Withdraw dose.

It is recommended that vigorous shaking be avoided during reconstitution; roll and tilt to enhance reconstitution. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

Administration:

When the following procedure is used to clear a central Venous catheter, the patient should be instructed to exhale

and hold his breath any time the catheter is not connected to I.V. tubing or a syringe. This is to prevent air from entering the open catheter.

Aseptically disconnect the I.V. tubing connection at the catheter hub and attach an empty 10 mL syringe. Determine occlusion of the catheter by *gently* attempting to aspirate blood from the catheter with the 10 mL syringe. If aspiration is not possible, remove the 10 mL syringe and attach a syringe filled with an amount of prepared ABBOKINASE OPEN-CATH solution equal to the internal volume of the catheter. Slowly and gently inject the ABBOKINASE solution into the catheter. Aseptically remove the syringe and connect a 5 mL syringe to the catheter. Wait at least 5 minutes before attempting to aspirate the drug and residual clot with the empty syringe. Repeat aspiration attempts every 5 minutes. If the catheter is not open within 30 minutes, the catheter may be capped allowing ABBOKINASE solution to remain in the catheter for an additional 30 to 60 minutes before again attempting to aspirate. A second injection of ABBOKINASE (urokinase for catheter clearance) may be necessary in resistant cases. When patency is restored, aspirate 4 to 5 mL of blood to assure removal of all drug and residual clot. Remove the blood-filled syringe and replace it with a 10 mL syringe filled with 0.9% Sodium Chloride Injection, USP. The catheter should then be gently irrigated with this solution to assure patency of the catheter. After the catheter has been irrigated, remove the 10 mL syringe and aseptically reconnect sterile IV. tubing to the catheter hub.

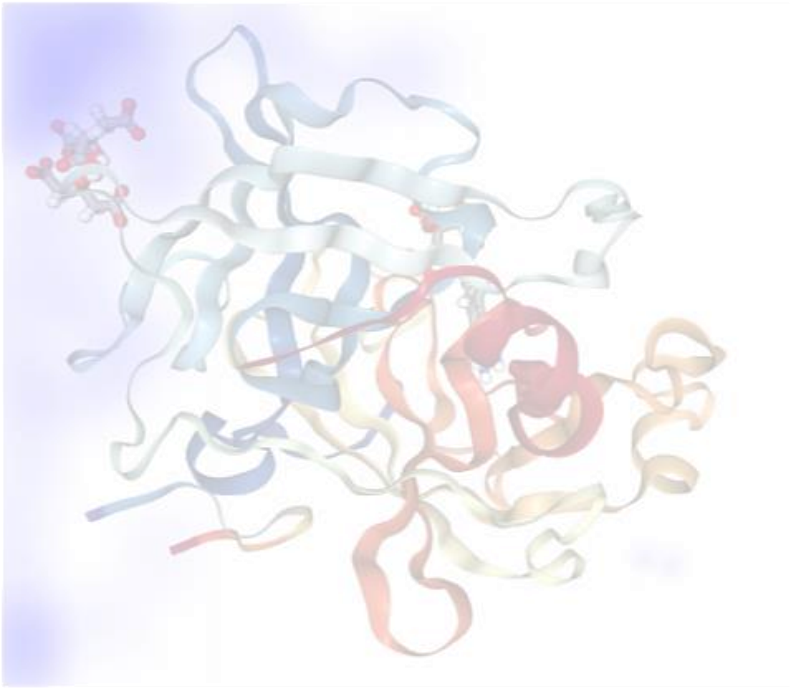
HOW SUPPLIED

ABBOKINASE OPEN-CATH (urokinase for catheter clearance) is supplied as a

sterile lyophilized preparation in single dose Univial® packages of 1 mL (NDC 0074-6111-01) and 1.8 mL (NDC 0074-6145-02). Store powder below 77°F (25°C). Avoid freezing.

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 3. Hurtubise MR, Bottino JC, Lawson M, et al. Restoring patency of occluded central venous catheters. *Arch Surg*. 1980; 115:212-213.
 4. Glynn MFX, et al. Therapy for thrombotic occlusion of long-term intravenous alimentation catheters. *Journal of Parenteral and Enteral Nutrition*. 1980; 4:387-390.
- S. Lawson M, Bottino JC, Hurtubise MR, et al. The use of urokinase to restore the patency of occluded central venous catheters. *Am J IV Ther and Clin Nutr*. 1982; 9:29-30,32.
- Revised: Aug., 1994
- Univial-Sterile two-compartment vial, Abbott.
- Ref. 06-9128-R8-Rev. August, 1994
- Abbott Laboratories**
North Chicago, IL 60064



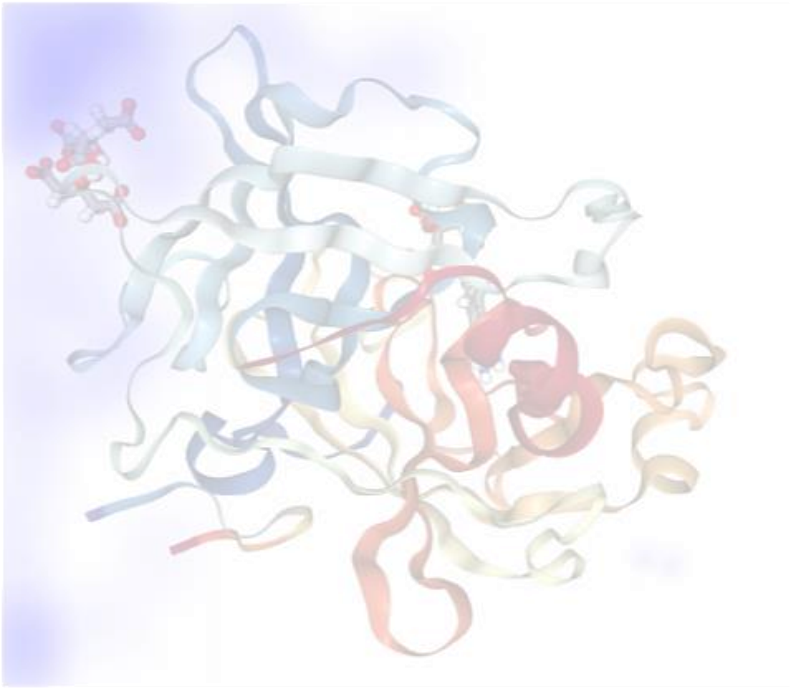
Appendix 5

CMO / CRO Strategy Pre and Post Commercial

Contract Strategy for Manufacturing, Testing and Development (cont'd)

Contribution of Candidate Vendors to Kinlytic Development and Manufacturing			
Pre and Post Approval			
Process and Testing Update and Installation	Drug substance development and installation in plant (Vendor A)	Finished drug product installation in plant (Vendor B)	Test method development and transfer to CMO's (Vendor C)
Pre-approval manufacture and testing	Drug Substance manufacture and testing for engineering, validation, clinical (Vendor A)	Drug Product manufacture and testing for engineering, validation, clinical (Vendor B)	Materials testing, in-process testing, additional release testing (Vendors D, E)
Characterization and comparability	Characterization and analytical comparability (Vendors C, E, A and B)	Non-clinical comparability (Vendor F)	Clinical comparability (Phase III) (Vendor G)
Commercial manufacturing and testing	Drug Substance (Vendor A)	Drug Product (Vendor B)	Additional In-process and release tests (Vendors D and E)
Microbix and/or Partner Coordination and Control of Vendors			

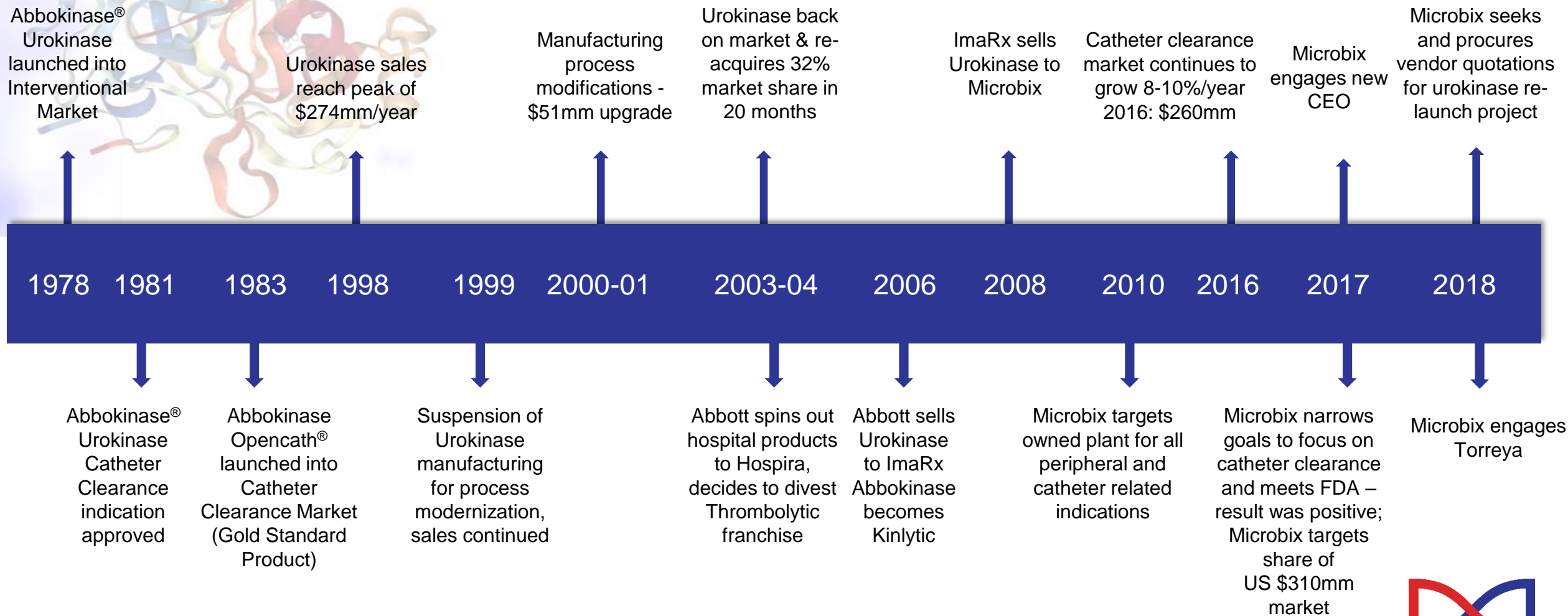
- The table indicates candidate vendors who contributed and validated Microbix' project budget and timeline
- It is expected that as the project proceeds, additional competitive bids will be obtained from alternate vendors

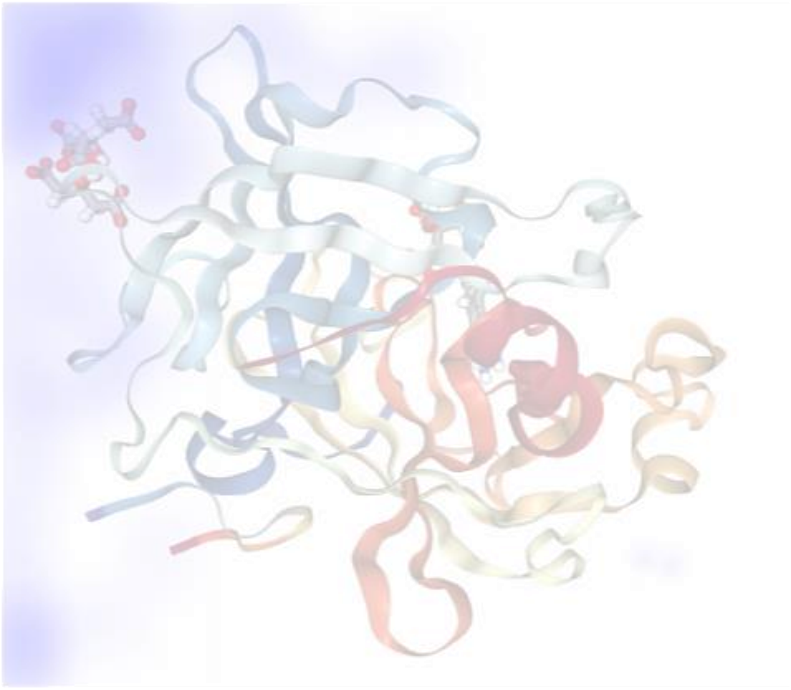


Appendix 6

Urokinase Historical Timeline

Kinlytic® Urokinase Business History Timeline





Appendix 7

Microbix and Post Transaction Support

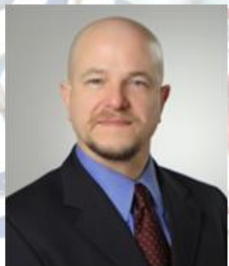
Kinlytic® Ownership – Introducing Microbix®

- Microbix Biosystems Inc. is based in Ontario, Canada - founded in 1988
- Microbix is a public company, listed on the Toronto Stock Exchange (TSX)
 - Manufactures viral, bacterial proteins and nucleic acids for use in diagnostic and quality assessment products
 - Sales of approximately CA\$1mm per month
 - Owns Kinlytic® urokinase
- Microbix' interest began over 20 years ago, when it sought to develop a “biosimilar” to Abbokinase®
 - Its core competencies in cell culture and purification are the same needed to produce urokinase
 - Those competencies and the economic opportunity drove its interest in creating a biosimilar
- In 2008, Microbix acquired all urokinase assets from ImaRx, making it the only source of LMW-UK globally
 - In 2006, ImaRx Therapeutics acquired the product from Abbott – selling inventory but not manufacturing
- Microbix has the assets and know-how needed to re-launch Kinlytic into the growing US market for CC
- Microbix is now seeking a partner to help enable the re-launch onto the US market by way of sNDA filing

Post Transaction Support

- Microbix is prepared to support Kinlytic's return to market with
 - Access to Kinlytic NDA / IND
 - Transfer of documentation and knowledge
 - Transfer of master cell banks and standards
 - Introduction to consultants and candidate CMO/CRO service providers
 - Key Microbix personnel can join project team as desired
- Other support could include, according to partner's preferences and transaction terms
 - Transfer of NDA / IND
 - Assist Partner with installation in an existing facility or with establishing a new facility
 - Manage restart and commercial manufacturing
 - Manage future master cell bank replenishment

The Microbix Team



Cameron Groome
CEO, President and
Director



Jim Currie
CFO



Kevin Cassidy
VP Biopharmaceuticals



Ken Hughes
COO



Phil Casselli
SVP Business
Development, Sales and
Marketing



Mark Luscher, Ph.D.,
SVP, Scientific Affairs



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Development



Bo Hollas
Director Quality
Assurance and
Compliance