WILMER, CUTLER & PICKERING

2445 M STREET, N.W. WASHINGTON, D.C. 20037-1420

TELEPHONE 12021 563-6000 1997 JUN 25 A 6: 22 CARLTON GARDENS

June 24, 1997

100 LIGHT STREET BALTIMORE, MD 21202 TELEPHONE (410) 986-2800 FACSIMILE (410) 986-2825

D: 22 CARLTON GARDENS LONDON SWIY SAA TELEPHONE OII (44171) 872-1000 FACSIMILE OII (44171) 839-3537

RUE DE LA LOI 15 WETSTRAAT 8-1040 BRUSSELS TELEPHONE OII 13221 285-4900 FACSIMILE OII 13221 285-4949

FRIEDRICHSTRASSE 93 D-10117 BERLIN TELEPHONE 011 (4930) 2022-6400 FACSIMILE 011 (4930) 2022-6500

GARY D. WILSON DIRECT LINE (2021 663-6279 INTERNET GWILSON@WILMER.COM

ه سرېر د ه تر د

By Hand Delivery

Barbara M. McGarey Deputy Director Office of Technology Transfer National Institutes of Health 6011 Executive Boulevard Rockville, MD 20852-3804

Re: <u>Petition of CellPro, Inc.</u>

Dear Ms. McGarey:

Enclosed are copies of the following court filings made in the ongoing district court litigation after the argument on the motion for injunction, a transcript of which I forwarded with my letter of May 8, 1997, to Robert B. Lanman:

1. May 15, 1997, submission by plaintiffs of revised "[Proposed] Order for Permanent Injunction and Partial Stay of Injunction."

2. May 28, 1997, submission by plaintiffs of letter "addressing CellPro's contact with clinicians who signed declarations at plaintiffs' request" and Declaration of Dr. Scott D. Rowley.

3. June 5, 1997, submission by CellPro of letter and accompanying declarations responding to item 1.

4. June 13, 1997, submission by plaintiffs of letter responding to item 3 and accompanying Supplemental Declaration of Dr. Jerry A. Hausman.

5. June 16, 1997, submission by CellPro of letter responding to item 2.

In addition, I am enclosing a copy of a Declaration of David F. Weeda. This Declaration was summarized in CellPro's opposition to plaintiffs' motion for injunction (Exhibit 2 to CellPro's April 24, 1997, submission) and referred to in my letter of May 8 to Mr. Lanman, but I do not believe the Department has previously received a copy of it.

Please let me know if you have any questions about the enclosed or if I may otherwise be of assistance.

Very truly yours,

han D, with

Gary D. Wilson

Enclosures

-

cc: Donald R. Ware (by fax, w/o enc.) Frederick G. Savage (by fax, w/o enc.) Robert B. Lanman (by hand, w/enc.)

#### WILMER, CUTLER & PICKERING

2445 M STREET, N.W. WASHINGTON, D.C. 20037-1420 100 LIGHT STREET BALTIMORE, MD 21202 TELEPHONE (4101 986-2800 FACSIMILE (4101 986-2828

GARY D. WILSON DIRECT LINE (202) 663-6279 INTERNET GWILSON@WILMER.COM

تم میم ر د م را

FACSIMILE (202) 663-6363

TELEPHONE 12021 563-6000 1997 JUN 25 A 6: 22 CARLTON GARDENS

CONDON SWIY SAA TELEPHONE ON (44171) 872-1000 FACSIMILE ON (44171) 839-3537

June 24, 1997

AUE DE LA LOI IS WETSTRAAT B- 1040 BRUSSELS TELEPHONE OII 1322: 285-4900 FACSIMILE OII 1322: 285-4949 FRIEDRICHSTRASSE 95

D-1017 957LIN TELEPHONE OII (4930) 2022-6400 FACSIMILE OII (4930) 2022-6500

## By Hand Delivery

Barbara M. McGarey Deputy Director Office of Technology Transfer National Institutes of Health 6011 Executive Boulevard Rockville, MD 20852-3804

Re: Petition of CellPro, Inc.

Dear Ms. McGarey:

Enclosed are copies of the following court filings made in the ongoing district court litigation after the argument on the motion for injunction, a transcript of which I forwarded with my letter of May 8, 1997, to Robert B. Lanman:

1. May 15, 1997, submission by plaintiffs of revised "[Proposed] Order for Permanent Injunction and Partial Stay of Injunction."

2. May 28, 1997, submission by plaintiffs of letter "addressing CellPro's contact with clinicians who signed declarations at plaintiffs' request" and Declaration of Dr. Scott D. Rowley.

3. June 5, 1997, submission by CellPro of letter and accompanying declarations responding to item 1.

4. June 13, 1997, submission by plaintiffs of letter responding to item 3 and accompanying Supplemental Declaration of Dr. Jerry A. Hausman.

5. June 16, 1997, submission by CellPro of letter responding to item 2.

In addition, I am enclosing a copy of a Declaration of David F. Weeda. This Declaration was summarized in CellPro's opposition to plaintiffs' motion for injunction (Exhibit 2 to CellPro's April 24, 1997, submission) and referred to in my letter of May 8 to Mr. Lanman, but I do not believe the Department has previously received a copy of it.

Please let me know if you have any questions about the enclosed or if I may otherwise be of assistance.

Very truly yours,

hay D, with

1

Gary D. Wilson

Enclosures

. . . .

cc: Donald R. Ware (by fax, w/o enc.) Frederick G. Savage (by fax, w/o enc.) Robert B. Lanman (by hand, w/enc.) RCV BY: Lyon & Lyon L. A.

: 6-13-97 :11:39AM :

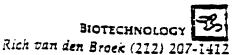
1 302 658 2508-

Lyon & Lyon L. A. :#16

Exhibit A

CellPro, Inc.

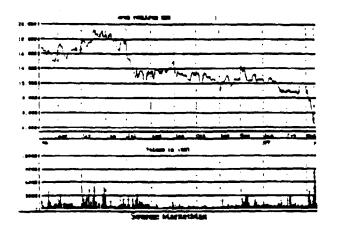
CPRO/FY ends Mar./S6 1/2) Notes: a. e. f Recommendation: Strong Buy H&Q



HAMBRECHT & QUIST LLC SPOT REPORT

March 13, 1997

# WILL THE PAIN EVER END? IT'S ALMOST OVER



Consistent with his actions throughout the case, we expect that the judge will rule in Baxter's favor and (1) treble the damages awarded by the jury, to a total of almost \$7 million, (2) award Baxter its legal expenses, which could total about \$15 million, but we would not be surprised if Baxter claimed they were higher, and (3) grant Baxter's request for an injunction.

Eventually, this patent case will be resolved, and we believe that the worst case scenario will involve CellPro paying a modest up-front fee and a modest royaity to Baxter along the lines of the previous licenses that were issued. We still believe that its more likely that CellPro will pay nothing and be free to sell the Ceptate system workdwide. The critical investment concern regarding CellPro, in our view, is what is the eventual size of the Ceptate business, and this question will not be answered definitively until the second half of 1997, when additional sales and clinical data will be released.

Estimates	01	Q2-	03	04	FY
'97 EPS					(\$1.52)
97 Revenues					\$13.7
98 EPS					(\$0.35)
'98 Revenues					541.8
Revenue Estimates in Millions					

## Review of Events

CellPro has lost over 40% of its marker value as the larest trial evolving from its patent dispute with Baxter/Becton Dickinson/Johns Hopkins has run its course, and investors are wondering when or more importantly if the slide will stop. Unfortunately, there is one more shoe to drop, which could come today, before this debacle concludes and CellPro can go on to appeal this case. A quick recap: On Tuesday afternoon the jury in the case awarded Baxter \$2.3 million, the maximum it was asking for, and following the judges predeliberation directions, found for willfulness. Yesterday, in a press release Baxter announced that it would seek to enjoin sale of the Ceprate system in the US (the patents do not cover Europe or Asia). Today there is a hearing to discuss enhanced damages stemming from the ruling.

## Yet Another Shoe to Drop?

Consistent with his actions throughout the case, we expect that the judge will rule in Baxter's favor and (1) treble the damages awarded by the jury, to a total of almost \$7 million. (2) award Baxter its legal expenses, which could total about 515 million, but we would not be surprised if Baxter claimed they were higher, and (3) grant Baxter's request for an injunction. All of these issues will not be determined at the hearing, especially the issue of the injunction, which will probably take a few weeks to be imposed. With all that news still ahead, why would anyone suil want to be an owner or buyer of CeilPro? First and foremost for the reason that we continue to believe that this highly unusual and unprecedented decision will be overturned upon appeal and that CellPro will prevail. Second, at this point we believe that this potential bad news has been discounted as likely to occur and is reflected in the stock price, which is near our estimated valuation of its cash and ex-US business. After today's hearing and the eventual imposition of the three penalties listed above. CellPro will finally be free to move on to the appeals process, under new jurisdiction.

#### Will Penaities Overwhelm CellPro?

Concern has arisen that if the total damages awarded to Baxter by the judge exceed \$20 million, and the product is enjoined from sale in the US, that CellPro will be unable to survive long enough to see the matter through the appeal. We believe that such concerns are unfounded. Whatever the eventual damages turn out to be, CellPro does not write a check for that amount. The standard practice is to purchase an appeal bond, which would cover the penalty until the appeal is resolved. If the judge issues an injunction. CellPro will receive expedited review (days to weeks) of its appeal of the injunction alone in a different court. We believe that an injunction would be rapidly overturned in the interest of the public health, and because it is a tough case to argue Baxter is being irreparably harmed since its competing system is not yet approved for sale in the US. If the injunction is overturned, the judge could order that CellPro pay, or set aside a royalty to Baxter that he determines reasonable. Regardless of what that rate is, we expect that CellPro will be tree to continue selling the product in the US, and more importantly will have more than sufficient resources to see the dispute through appeal.

## Baxter's Filing Not a Real Concern

Another area of concern is that Baxter's competitive cell separation system. Isolex 300, could be much closer to US approval than we had esumated. As we mentioned in an earlier report, during the trial Baxter surprised many -(including us) when it stated that it had filed a PMA with the FDA seeking US approval. We continue to maintain our belief that this PMA is simply a strategic move to improve the appearance of its competitive position, and has little chance of approval. Baxter has been developing the Isolex 300 for about as long as CellPro has been developing Ceprate. Both received CE Mark authorization to sell the product in Europe in 1995. Even though Baxter received CE Mark six months ahead of CellPro, since that time CellPro has achieved over 80% estimated market share in Europe with a salesforce about 1/10th the size. In its recent press release. Baxter stated that over 800 patients have been treated with cells processed with the Isolex 300 system since its introduction, as compared to over 5,000 patients treated with Ceptate purified cells. Both these facts would confirm our view of CellPro's Ceprate as the superior product. The majority of patients for both companies has been in Europe in our opinion. To our knowledge, Baxter has not initiated a pivotal trial in the US. Based on precedent, we would expect such a trial to include 100-200 patients, be randomized with one arm of patients receiving Isolex-processed cells and one arm receiving unprocessed cells. We would expect this trial to take about one year to enroll, and the FDA requires one year follow up of all patients. With six months to compile and file the data and six months for FDA review results in three year total time from pivotal trial initiation to approval. There is a chance that Baxter has had such a trial underway below the market's (and our) radar screen for the past few years, but we view the likelihood of that as next to nil. Most likely in our opinion, Baxter's PMA consists of an non-randomized collection of European patients treated with cells from the Isolex 300 matched against historical controls. We could not foresee under any circumstances the FDA accepting such a PMA filing, much less approving it.

The Isolex 300 system that Baxter has filed for approval is actually the first generation product using its technology. In the fall of 1996, the company introduced its re-engineered Isolex 300i system, which we view ar a significant improvement of the technology. In contrast to CellPro proprietary avidin-biotin system. Baxter utilizes a magnetic bead separation technology. Magnetic beads are very effective at selecting desired subpopulation of cells, and are especially well suited for negative selection, or purging certain cells. However, for positive selection, where the selected cells are intended to be given back to the patient, the magnetic beads

HAMBREDIT & QUET SPOT REPORT

must be removed from desired cells prior to reinfusion, making it a much more complicated processing. With the first-generation isolex 300 system, the magnetic beads are released from the desired cells with an enzyme called "hymopapain, which quite simply digests all the proteins on the outside of the cells. While it is an effective technique to remove the magnetic beads, external proteins are important to cell growth and signaling. Baxter claims that these external proteins regenerate in a short period of time, but there is evidence that enzyme exposure damages the cells and inhibits their growth. Baxter itself provides further confirmation of the shortcomings of using enzyme release technique. In addition to significant engineering alterations the new Isolex 300i has eliminated the chymopapain and uses a proprietary peptide release technology that drops the beads off the cells without damaging the important extra-cellular proteins. Baxter researchers presented evidence at the American Society of Hematology (ASH) meeting in 1995 that cells from the new peptide release technology showed a significant increase in *in vitro* expansion as compared to chymopapain released cells. Since the peptide release system does not have any stimulatory activity on its own, these data appear to confirm the theory that chymopapain can be harmful to cells. The bottom line is that while the new Isolex 300i is a significant improvement in our view as compared to the older Isolex 300, the PMA submitted is from data using the first generation technology, which we believe has little chance of ever gaining approval.

#### Baxter's Strategy

Baxter has been widely reported to be attempting to sell the division developing the Isolex 300 and 300i systems, We feel it highly unlikely that a large third party (such as Amgen. Novartis. Rhone Poulenc Rorer, etc.) with a potential interest in Baxter's business and technology would be willing to purchase this business until this legal dispute with CellPro is resolved one way or another. A smaller buyer with lesser resources would be even less willing to take on the potential risk, in our view. As a result, we believe Baxter believes it imperative to resolve this dispute as soon as possible. If Baxter can bring enough pressure to bear on CellPro to force them to take a license to the patents, it would (1) further validate the patents' value and thereby Baxter's franchise, (2) remove the risk that the patents are ruled invalid on appeal, and (3) end this lawsuit, greatly improving the likelihood of a sale of its division. If, however, CellPro holds fast and pursues the matter in the appellate court, which we "xpect, then Baxter must support the division for about another year, which would include paying additional egal expenses. The stakes could be even higher for both parties. If CellPro prevails upon appeal and the original jury verdict is reinstated, which we believe to be likely, then CellPro can pursue the next leg of its lawsuit. CellPro has claimed that Baxter misused the patents in question in an attempt to extract European and Japanese marketing rights to the Ceprate system. If Baxter loses that case, the damages could be large in CellPro's. Even if CellPro had to put aside a \$25 million penalty and was blocked from the US market, the \$35 million in remaining cash could last them at least two years (longer if it cuts back on clinical development expenses), which would be more than enough time for the appeal court to rule on the case. When the current proceedings are concluded in the next few weeks, regardless of how onerous the outcome for CellPro, we do not believe Baxter will have enough leverage to force CellPro's hand to license the patents and end the dispute, and thereby Baxter will have to see the matter through appeal.

#### The Court Would Like to Thank the Jury for ....

What is especially unusual about this case in our opinion is that the judge, not the juries, has determined the outcome. There are four critical issues in this (and many other) patent case: (1) the validity of the patents in question, (2) the infringement of the patents, (3) the willfulness of infringement, (4) and damages that should be awarded due to the infringement. In the original trial of the dispute between CellPro and Baxter a jury unanimously found regarding the first issue that the patents were invalid for reasons of lack of enablement and obviousness. On the second issue, the jury determined that CellPro did not infringe the patents anyway. Obviously this decision negated the need to deliberate the latter two issues. However, the judge chose not to enter this jury decision, but before sending it back to trial before another jury, he overruled the jury's decision, ruling first that the patents were valid and second that CellPro infringed these patents. Following these rulings, the judge stated that the jury's deliberations in the second trial (which concluded this week) would be limited to the issues of willfulness and damages. Even though we view the issues of validity and infringement to be the most important, the last two issues were also effectively determined by the judge. On the third issue as to

the there the patents were willfully infringed, the judge instructed the jury prior to its deliberations, that "any casonable jury" would find for willfulness, which in our view predetermined the outcome of that decision. On the final issue of damages, the jury awarded \$2.3 million, the maximum in their power but not of significance to CellPro, which has about \$60 million in cash. However, the judge has the authority to treble these damages, and due to the finding of willfulness, can award Baxter legal fees which could amount to \$15 million or more, which

HAMMERCHT & QUIE SPOT REPORT

could bring the total near S25 million, which is greater than CellPro has received in total revenues from international Ceprate sales over the past three years. Effectively, the judge can impose a penalty on CellPro that will be 10X what the jury awarded, which could have a dramatic impact on CellPro's future. Finally, this same judge can grant Baxter's motion for injunction, removing the Ceprate system from the US markets. As we stated above, we believe it likely that the judge takes all these measures. If these events transpire as it appears they will, it begs the question as to why two junes were involved in this dispute at all.

#### Summary

Eventually, this patent case will be resolved, and we believe that the worst case scenario will involve CellPro paying a modest up-front fee and a modest royalty to Baxter along the lines of the previous licenses that were issued. We suil believe that its more likely that CellPro will pay nothing and be free to sell the Ceprate system worldwide. The critical investment concern regarding CellPro, in our view, is what is the eventual size of the Ceprate business, and this question will not be answered definitively until the second half of 1997, when additional sales and clinical data will be released.

#### Company Overview

CellPro has several products and product candidates in therapeutic. diagnostic. and research applications based on its proprietary cell separation technology, called CEPRATE. The lead therapeutic product of the company is the CEPRATE SC system, a unique system that can be used to separate a small number of specific cells from complex cell mixtures for use as a transplant to rescue patients from infections and bleeding in high dose cancer chemotherapy (HDCT). These cells are the early-stage cells in blood that divide and change many times to replace all cells in the blood, red, white and platelets as they mature and die. The CEPRATE SC is designed to purify the small fraction (<1%) of these cells from the a patient's 200-500 mi "buffy coat." the white blood cell mixture collected from either the bone marrow or peripheral (circulating) blood. The resulting small (5 mi) CD34+ enriched cell suspension contains all the cells necessary for a successful transplant, and greatly reducer the toxicity, storage and malignant cell problems caused by unpurified buffy coat progenitor cell transplants (PCTs), which are the current standard of care. We believe that CellPro's device provides a crucial incremental benefit to the existing transplant market and that will eventually allow a new, more broadly applicable market to emerge of therapy for cancer to become more accepted and more widely used. That new therapy is high dose chemotherapy (HDCT) enabled by peripheral blood progenitor cell (PBPC) support.

		Netes	
Additional companies managened in this report:			
Symbol	Name	Notes	
Amerik Balar Bestus Dicklassen	AMON BAX BOX RPR		
<ul> <li>Hambrecht &amp; Quist LLC maintains a m</li> <li>The analysis covering these stocks have</li> <li>Options are available on these issues.</li> </ul>			-

HAMMAGINT & QUET SPOT REPORT

:

Exhibit B

RESULTS FOR FISCAL 1997 - MAY 14, 1997



#### CELLPRO REPORTS RESULTS FOR FISCAL 1997

#### FOR IMMEDIATE RELEASE

Contact: Joann Reiter

CellPro Incorporated

(206) 485-7644

e-mail: invest@celloro.com

#### Special advisory: This news release contains forward-looking statements.

#### **CELLPRO REPORTS RESULTS FOR FISCAL 1997**

SEATTLE – May 14, 1997 – CellPro, Incorporated (NASDAQ: CPRO) today reported a net loss of S24.1 million, or \$1.67 per share, for its fourth fiscal quarter ended March 31, 1997, and a net loss of s40.9 million, or \$2.84 per share, for the 1997 fiscal year. The net loss for the fourth fiscal quarter and for the fiscal year includes a \$17 million charge related to on-going patent litigation. Excluding this charge, net loss would have been \$7.1 million, or \$0.49 per share, for the fourth fiscal quarter and \$23.9 million, or \$1.66 per share, for the fiscal year ended March 31, 1997. This compares with a net loss of \$5.3 million, or \$0.37 per share, and \$15.7 million, or \$1.13 per share, for the fourth fiscal quarter and fiscal year ended March 31, 1997, the Company's cash, cash equivalents and marketable securities totaled \$54 million. Shares issued and outstanding at the fiscal year-end totaled 14.5 million.

CellPro reported \$3.1 million in product sales for the fourth fiscal quarter and \$9.5 million in product sales for the fiscal year ended March 31, 1997. This compares with \$2.3 million and \$6.8 million for the fourth fiscal quarter and the fiscal year ended March 31, 1996, respectively. Increased sales of the CEPRATE® SC Stem Cell Concentration System accounted for the improvement. The CEPRATE® SC System is used to provide stem cells to repopulate the bone marrow of patients being treated for diseases such as breast and ovarian cancer, lymphoma, multiple myeloma and acute hematological malignancies. The CEPRATE® SC System is approved for use in the United States, the 18-nation European Economic Area and Canada, and is commercially available in other European countries and in several countries in the Asia Pacific region and Latin America.

Research and development expense totaled \$4.2 million and \$16.2 million for the fourth fiscal quarter and the fiscal year ended March 31, 1997, respectively. Research and development expense was \$4.3 million and \$16.5 million for the prior year's fiscal quarter and year ended March 31, 1996, respectively.

The Company has completed patient enrollment in a Phase III trial designed to demonstrate the CEPRATE SC System's ability to deplete tumor cells from peripheral blood stem cell transplants in patients being treated for multiple myeloma. This clinical trial is in the post-treatment patient follow-up phase. Additionally, in October 1996, the Company began a multicenter Phase I/II clinical trial utilizing

06/02/97 15:31:42

#### RESULTS FOR FISCAL 1997 - MAY 14, 1997

http://www.cellpro.com/rsultf97.htm

phase. Additionally, in October 1996, the Company began a multicenter Phase I/II clinical trial utilizing the CEPRATES SC System together with a new second generation product, the CEPRATES TCD T-Cell Depletion System, for mismatched allogeneic transplantation in children with leukemia. Trial subjects are children who need stem cell transplants, but for whom no matched-donor can be found. These children typically do not have any other viable treatment option. The CEPRATE3 SC System is also being used to deplete T cells from stem cell products used to repopulate the marrow of patients receiving marrow-killing chemotherapy to treat certain autoimmune disorders including multiple sclerosis, rheumatoid arthritis and lupus. The CEPRATES SC System is being used in numerous additional clinical trials, including applications in dose-intensified, multicycle chemotherapy to treat solid-tissue tumors and allogeneic matched- and mismatched-donor trials to treat leukemias. Further, the Company is participating in various gene therapy trials in which the CEPRATEA SC System is used to concentrate stem cells to enhance the efficiency of gene insertion to treat genetic disorders and diseases such as cancer, AIDS and severe combined immunodeficiency (SCID). Additional research and development is underway to develop a number of new products for use in cellular therapeutics and cancer diagnostics.

Selling, general and administrative expenses increased to \$5.0 million and \$15.4 million for the fourth fiscal quarter and the fiscal year ended March 31, 1997, respectively. This compares with \$3.1 million and \$12.5 million for the fiscal quarter and the fiscal year ended March 31, 1996. The increase in fiscal year 1997 expenses resulted primarily from higher legal fees and sales and marketing expenses. Legal fees were incurred to defend the Company in patent litigation brought jointly by Baxter Healthcare Corporation, Becton Dickinson & Co. and Johns Hopkins University against the Company, discussed further below. Increased sales and marketing expenses resulted from activities in support of commercialization of the CEPRATE® SC System in the United States and Europe. The US product launch began in December 1996 following FDA approval of the CEPRATE® SC System for purification of stem cells for bone marrow transplantation. The CEPRATE® SC System is the only cell processing system which has been approved by the FDA for this indication.

At March 31, 1997, the Company established an accrual of \$17 million to cover potential losses from, and future expenses for, on-going patent litigation. CellPro is optimistic that it will ultimately prevail in this dispute, however, the reserve has been made in recognition of the fact that a judgment against the Company is currently pending at the federal district court level. The amount of damages have not yet been decided by the court. The Company believes that a number of reversible errors have been made by the court, and that the judgment against the Company is contrary to the evidence and facts of the case. As a result, the Company intends to appeal this judgment vigorously. The ultimate amount of damages, if any, and the ultimate amount of future expenses incurred in pursuing this litigation may vary significantly from the amount reserved.

The Company also reported interest income totaling \$779,000 for the fourth fiscal quarter and \$3.6 million for the fourth fiscal quarter and the fiscal year ended March 31, 1997, respectively. In the prior period, the Company earned \$1.1 million and \$4.2 million for the fiscal quarter and the fiscal year ended March 31, 1996, respectively. The decrease was due to lower average cash balances available for investment in the current year.

This news release contains forward-looking statements. However, the Company's business involves risks and uncertainties that could cause actual results or events to differ materially from those in such forward-looking statements. Potential risks and uncertainties include, without limitation, those mentioned in CellPro's Annual Report on Form 10-K for the fiscal year ended March 31, 1996, and CellPro's quarterly reports on Form 10Q for the fiscal quarters ended December 31, 1996, September 30, 1996 and June 30, 1996 under the heading "Investment Considerations" and in CellPro's other public filings. Particular attention should be given to the Investment Considerations labeled

RESULTS FOR FISCAL 1997 - MAY 14, 1997

"Uncertainty of Product Acceptance" and "Legal Proceedings" in CellPro's Annual Report on Form 10-K for the fiscal year ended March 31, 1996.

CellPro, Incorporated is a biotechnology company in Bothell, Washington specializing in the development, manufacturing and marketing of proprietary continuous-flow, cell-selection systems for use in a variety of therapeutic, diagnostic and research applications.

## **Financial Summary Follows**

#### CELLPRO, INCORPORATED

(a Company in the development stage)

SELECTED FINANCIAL DATA

Statement of Operations Data:

(unsudited)

	Three Months Ended		Year Ended	
	March 31,		March 31,	
	1997	1 <b>996</b>	1 <b>997</b>	1996
Revenues:				
Product sales	\$3,128,228	\$2,309,185	\$9,515,984	<b>\$6,8</b> 01,985
Related party revenue				6,000,000 *
Contract and other revenue	80,559		146,390	41,600
Total revenue	3, <b>208,787</b>	2,309,185	9, <b>662,374</b>	12, <b>843,585</b>
Costs and expenses:				
Cost of product sales	1, <b>596,895</b>	1,275,172	5,161,389	3,723,421
Research and development	4, <b>188,03</b> 1	4, <b>307,08</b> 3	16,243,501	16,474,133

06/02/97 15:31:43

,								
RESULTS	FOR	<b>FISCAL</b>	1997	-	KAY	14,	1997	

http://www.cellpro.com/reultf97.htm

L.

Selling, general and administrative	4,995,660	3,097,890	15,379,650	12,515,870
Litigation provision	17,000,000		17,000,000	
Total costs and expenses	27,780,586	8,680,145	53,7 <b>84,54</b> 0	32,713,424
Loss from Operations	-2 <b>4,5</b> 71,799	- <del>6</del> ,370,9 <del>60</del>	-44,122,166	-19,869,839
Other income (expense):				
Interest income	778,726	1,0 <b>82,849</b>	3,590,157	4,164,218
Interest expense	-7,413	-15,099	-46,053	-86,718
Other, net	-30 <b>8</b> ,34 <b>5</b>	-15,915	-337,323	139,679
Total other income	462,965	1,051,835	3,206,781	4,217,179
Net loss	(\$24,108,834)	(\$5,319,125)	( <b>\$</b> 40,915 <b>,385</b> )	(\$15,652,660)

Net loss per share	( <b>\$1.6</b> 7)	( <b>\$0.37</b> )	(52.84)	(\$1.13)
				<del></del>
Weighted average number of shares outstanding	14,478,735	14,282,214	14,421,908	13, <b>847,929</b>

March

31,1996

March 31,1997

Balance Sheet Data:

06/02/97 15:31:44

## RESULTS' FOR FISCAL 1997 - MAY 14, 1997

http:/	//www.cellpro.com/rsultf97.ht	
--------	-------------------------------	--

Cash, cash equivalents and marketable securities	\$54,043,175	\$74,143,851
Total assets	76,123,697	97,941,349
Long-term debt, net of current		
portion	152,943	206,001
Total stockholders' equity	52,780, <del>64</del> 8	92,213,233

\* This is non-recurring revenue received for prior research and development services rendered by CeilPro as part of the termination of business arrangements between CellPro and Corange International Ltd.

## Return

06/02/97 15:31:44

Exhibitc

#### FOLEY, HOAG & ELIOT LLP ONE POST OFFICE SQUARE BOSTON, MASSACHUSETTS 02109-2170

Donald R. Ware (617) 532-1167 dware@fbe.com TELEPHONE 617-832-1000 FACSIMILE 617-832-7000 http://www.fhe.com :615 L STREET, N.W., SUITE 650 WASHINGTON, D.C. 20036 TEL: 202-775-0600 FAX: 202-857-0140

June 10, 1997

#### VIA FAX

Coe A. Bloomberg, Esq. Lyon & Lyon First Interstate World Center 633 West Fifth Street, Suite 4700 34th Floor Los Angeles, CA 90071

Dear Coe:

In our telephone conference with Judge McKelvie last week, you represented that CellPro wished to file only a "short letter" with the Court on Friday, and did not propose to file any affidavits. This representation obviously was untrue, as CellPro filed not only a letter but also three declarations.

With respect to the Cuiver declaration, if CellPro means to rely on it for any purpose, please provide the following documents and information so that they are received in our office by courier no later than Thursday morning of this week:

- 1. A list of the U.S. sites which have one or more Ceprate<sup>®</sup> SC devices installed and in use, and the date (actual or approximate) on which an SC device was first installed there.
- 2. Documents sufficient to show the number of units of SC disposable kits delivered to each such site on a monthly basis from 4/1/96 through 5/31/97.
- 3. Documents sufficient to show, with respect to each of the units identified in response to § 2, whether such unit was sold commercially pursuant to the approval granted by the FDA in December 1996 or rather was provided to the site for use in an approved clinical trial.

## Coe A. Bloomberg, Esq. June 10, 1997 Page 2

4.

Documents sufficient to show the prices actually charged by CellPro for each of the units described in ¶ 2, including information sufficient to show whether particular units provided for use in a clinical trial were provided on a cost-recovery basis or for free.

5. Documents sufficient to show, for each site at which the Ceprate® SC is installed and in use outside the United States, the disposable units sold and the prices actually charged by CellPro, on a monthly basis for the period 4/1/96 through 5/3 1/97.

- 6. CellPro's actual sales reports of Ceprate SC devices and disposable kits, on a quarterly basis and for April and May 1997, encompassing the period 4/1/96 through 5/31/97, in the most detailed form in which such records exist.
- 7. CellPro's current price list(s), by geographic area, for the SC device and disposable kits.
- 8. Documents sufficient to show the amount currently charged by CellPro to clinical sites for disposable kits provided on a cost recovery basis.
- All documents prepared between 4/1/96 and the present which discuss actual prices or projected or contemplated price increases for the SC device or disposable kits.
- 10. CellPro's budget for its fiscal year 1998, prepared prior to 3/12/97, and any revision thereof subsequently prepared.
- 11. CellPro's most recent business or strategic plan prepared prior to 3/12/97, and any revision thereof subsequently prepared.
- 12. Any sales projections (units and/or dollars) prepared between 12/1/96 and the present with respect to SC devices or disposable kits.
- Any projections of profitability prepared between 12/1/96 and the present.
- 14. Documents sufficient to define or explain the specific components of expense subsumed in the categories of expenses listed in the exhibits

Coe A. Bloomberg, Esq. June 10, 1997 Page 3

attached to Mr. Culver's declaration, including a specific breakdown of the "Special Items and Other" category for each fiscal year shown.

- 15. Documents sufficient to show the expense category in which Mr. Culver's exhibits include "Royalties and Fees Paid to Johns Hopkins" or "Incremental Profit Paid to Baxter."
- 16. Documents sufficient to show, by specific type of expense, the projected changes in each of the general expense categories shown in Mr. Culver's exhibits in the periods from fiscal 1996/97 to 1997/98 and from 1997/98 to 1998/99.
- 17. Documents sufficient to show the detailed calculation of "Royalties and Fees Paid to Johns Hopkins" and "Incremental Profit Paid to Baxter" projected in Mr. Culver's exhibits.
- 18 Documents sufficient to show the breakdown of "Patient Treatments --Commercial & Clinical" as between projected commercial units and projected units provided for use in clinical trials under the heading "Therapeutic 12.8 Disposables" shown in Mr. Culver's exhibits.
- 19 With respect to projected commercial units, CellPro's estimate of the breakdown, in each fiscal year, between units used by the customer in processing autologous bone marrow pursuant to CellPro's FDA approval, and units used for "off-label" purposes.
- 20 With respect to projected clinical units, CellPro's estimate of the breakdown, in each fiscal year, between disposable kits provided on a cost recovery basis and disposable kits provided for free.
- 21. If CellPro's projections assume FDA approval for additional uses not covered by CellPro's FDA approval in December 1996, the assumptions made concerning the dates of CellPro's application for approval of such uses and the dates of the FDA's grant of such approvals.
- 22. A description of the nature and amount of "external financing" assumed in Exhibits A-1 and A-2 to cover CellPro's projected cash deficiency.

Coe A. Bloomberg, Esq. June 10, 1997 Page 4

In view of the Court's indication that it intends to make resolution of the pending motions a high priority, we must insist on receiving these documents and other information on the timetable requested. If CellPro is unwilling to produce these materials, its refusal to do so will constitute further reason for the Court to disregard Mr. Culver's declaration.

Sincerely yours,

Donald R. Ware

DRW/kaw

. . .

#### CERTIFICATE OF SERVICE

I, William J. Marsden, Jr., hereby certify that on this 13th day of June, 1997, copies of the within document were caused to be served on the attorneys of record at the following addresses as indicated:

## VIA HAND DELIVERY

Gerard M. O'Rourke, Esquire Connolly, Bove, Lodge & Hutz 1220 Market Street Post Office Box 2207 Wilmington, Delaware 19801-2207

## VIA FEDERAL EXPRESS

Coe A. Bloomberg, Esquire Lyon & Lyon 633 West Fifth Street, 47th Floor Los Angeles, California 90071

William J. Marsden, Jr.

CHARLES & GROMPTON, JR. ROBERT K. PAYSOH LEONARD & TOGMAN RICHARD & POQUE NICHAEL D. GOLDMAN JAMES F. BURNETT DANIEL F. WULLOTT, JR. DANIE J. BARGWN BOMERS S. PRICE, JR. GREGORY A. INSKIP DANIE J. MORTH GREGORY A. INSKIP DANIE J. JAMES W. MARGING DRANE, JR. MICHAEL S. TUMAS NATHLER UNER MEDONOUGH LAURIE SELSER BUVERSTEIN FETER J. WALSH. JR. STEPHEN C. NORMAN MICHAEL S. BONKY MARGUE J. BALMONS. III MILLIAN R. BENKY

NITER'S DIRECT

OHAL (302) 984-6043

1 . - . .

Potter Anderson & Corroon

DELAWARE TRUST BUILDING P.O. BOX 981 WILMINGTON, DELAWARE 19899 (302) 984-6000 TELECOPIER (302) 684-1192 INTERNET: ATTYS PACOELAWARE.COM

May 28, 1997

AUNO P. SINCLAR BUILT P. SINCLAR HUGH CORROON HUGH CORROON RICHARD L. HOMARON AF COMMEN TO STABLE F. JA. COMEL

وريان بالمنافية والالارية المادية وسا

FREDERICK M. ALTERGOTT FETER L. TRACEY JENNIFER GMLER BRADY SCOTF E WAIMAN JOANNE CEBALLOS WENDY R. VOSE KEVIN R. SHANNON TODO L. GOOGMAN MICHAEL S. MEGNINISE JUCY ROTER MAY JUCY ROTER MAY SEMILIE RALARENAM ANDREW T. O'HEILL GREEGRY M. JONNSON

------

#### VIA HAND DELIVERY

The Honorable Roderick R. McKelvie United States District Court for the District of Delaware 844 King Street Wilmington, Delaware 19801

> Re: The Johns Hopkins University, et al. v. CellPro Civil Action No. 94-105-RRM

Dear Judge McKelvie:

We are enclosing for the Court's consideration prior to the teleconference we are rescheduling from this Friday to next week, a letter from our lead counsel, Donald R. Ware, addressing CellPro's contact with clinicians who signed declarations at plaintiffs' request.

Respectfully,

Iml Joanne Ceballos

JC/ja

Clerk of the United States District Court (w/enclosure) (Via Hand Delivery)
Coe A. Bloomberg, Esquire (w/enclosure) (Via Facsimile and U.S. Regular Mail)
Gerard M. O'Rourke, Esquire (w/enclosure) (Via Hand Delivery)
Donald R. Ware, Esquire (w/enclosure) (Via Facsimile and U.S. Regular Mail)
Steven J. Lee, Esquire (w/enclosure) (Via Facsimile and U.S. Regular Mail)
Michael Sennett, Esquire (w/enclosure) (Via Facsimile and U.S. Regular Mail).

## CERTIFICATE OF SERVICE

I, Joanne Ceballos, hereby certify that on this 28th day of May. 1997, a true and correct copy of the within document were served on the following attorneys of record as indicated:

## VIA HAND DELIVERY

1

Gerard M. O'Rourke, Esquire Connolly, Bove, Lodge & Hutz 1220 Market Street Post Office Box 2207 Wilmington, Delaware 19801-2207

## VIA FEDERAL EXPRESS

Coe A. Bloomberg, Esquire Lyon & Lyon 633 West Fifth Street, 47th Floor Los Angeles, California 90071

00-Joanne Ceballos

## **CERTIFICATE OF SERVICE**

I, Gerard M. O'Rourke, do hereby certify that on June 5, 1997, I caused to be served a copy of the foregoing DECLARATION OF JERROLD B. REILLY AUTHENTICATING DECLARATION OF LARRY CULVER IN OPPOSITION TO PLAINTIFFS' MOTION FOR A PERMANENT INJUNCTION AND IN SUPPORT OF ALTERNATIVE MOTION FOR STAY OF INVENTION PENDING APPEAL upon the following counsel of record by the means indicated:

BY HAND:

· · · ·

William Marsden, Esquire POTTER, ANDERSON & CORROON 350 Delaware Trust Building Wilmington, DE 19801

## BY FEDERAL EXPRESS:

Steven Lee, Esquire KENYON & KENYON One Broadway New York, NY 10004

Michael Sennett, Esquire BELL, BOYD & LLOYD 70 West Madison Street Chicago, IL 60602

Donald R. Ware, Esquire FOLEY, HOAG & ELIOT One Post Office Square Boston, MA 02109

Gerard M.

Del. I.D. Number 3265

## **CERTIFICATE OF SERVICE**

I, Gerard M. O'Rourke, do hereby certify that on June 5, 1997, I caused to be served copies of the foregoing SUPPLEMENTAL DECLARATION OF DR. MONICA S. KRIEGER IN OPPOSITION TO PLAINTIFFS' MOTION FOR PERMANENT INJUNCTION AND IN SUPPORT OF ALTERNATIVE MOTION FOR STAY OF INJUNCTION upon the following counsel of record by the means indicated:

## BY HAND:

William Marsden, Esquire POTTER, ANDERSON & CORROON Hercules Building Wilmington, DE 19801

## **BY FEDERAL EXPRESS:**

Steven Lee, Esquire KENYON & KENYON One Broadway New York, NY 10004

Michael Sennett, Esquire BELL, BOYD & LLOYD 70 West Madison Street Chicago, IL 60602

Donald R. Ware, Esquire FOLEY, HOAG & ELIOT One Post Office Square Boston, MA 02109

Gerard M. O

Del. I.D. Number 3265