Perimeter Medical Imaging | PINK-TSXV

Update

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PINK-TSXV

Rating:	Speculative Buy
Target:	$3.00
Price:	$0.32
Return:	838%
Valuation:	NPV, 20x EPS, 12.5x EV/EBITDA (F2030 estimates, 25% disc)

Market Data

Basic Shares O/S (M)	131.1
FD Shares O/S (M)	193.7
Market cap, basic (M)	42.0
Ent Val, basic (M)	39.7
Cash (recent Q; $CM)	2.3
Debt (recent Q, C$M)	0.0
52 Week Range	$0.17-$0.63
Avg. Weekly Volume (000)	552.8
Fiscal Year End	12/31/2025

Recent milestone

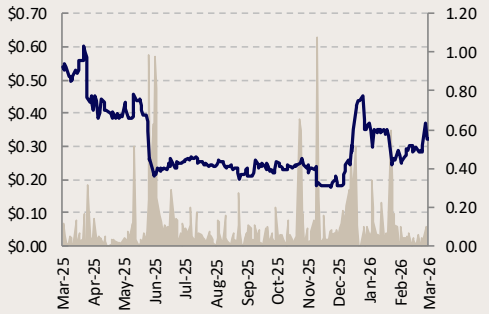
510(k) approval, OCT (met in Mar-21)	Q121
S-Series OCT, US commercial launch	Q121
ImgAssist, pivotal trial commencement	Q421
B-Series, PMA filing	Q125
B-Series, FDA approval	Q126

Financial Metrics

In US$000	2028E	2029E	2030E
OTIS, capital equip.	8,222	10,429	13,380
OTIS, consumable	17,045	35,979	75,256
Serv, grant, lease rev	4,549	6,815	9,838
Total revenue	29,817	53,223	98,474
EBITDA	3,414	20,528	53,980
EPS (basic)	$0.02	$0.12	$0.31
EPS (fd)	$0.02	$0.09	$0.24
P/E	*17.8x*	*3.5x*	*1.4x*
EV/EBITDA (basic S/O)	*8.3x*	*1.4x*	*0.5x*

Company Description

Perimeter Medical is an ON-based medical technology firm focused on developing its breast tumor margin assessment platform S-Series & its next-generation AI-enabled B-Series (CLAIRE) platform (FDA-approved in Mar/26).



Source: Refinitiv, Leede Financial

AI-Enabled B-Series OCT Platform Receives Formal FDA Approval As Our Model Projected – Spec Buy

ON-based breast tumor imaging platform developer Perimeter Medical Imaging received FDA approval for its artificial intelligence (AI)-enabled optical coherence tomography (OCT)-based tumor margin-visualization B-Series platform, presumably with positive FDA regard based on its own analysis of Perimeter's 206-patient breast tumor margin assessment trial completed last year.

In that study, Perimeter conclusively showed that B-Series/OCT-based margin assessment of excised breast tumors for women undergoing partial or radical lumpectomy surgery was able to identify in real time a sizable proportion of assessable patients who had residual tumor margins requiring further tissue removal from the surgical site, thus mitigating the need for future surgery to accomplish the same goal. Perimeter's PMA filing for B-Series based on these data were submitted in Mar/25 so review timelines were reasonable & in line with our expectations.

We long believed that B-Series clinical performance merited positive regulatory regard & so FDA approval is largely infused into our model already. As originally described in a Nov/25 update on the 206-patient pivotal trial indicated above, B-Series was in real time able to analyze margins of excised breast tumor masses during lumpectomy surgery & determine if supplemental tumor mass needed to be removed, with accuracy of 88.1%, meaning that the probability that B-Series missed residual disease [false-negative] or mis-identified healthy tissue as residual disease [false positive] was quite low & to a sufficiently significant degree to justify the positive FDA regard just conferred.

- This statistical assertion was based in part on the study's observation that B-Series was able to correctly identify a sizable proportion of patients for whom standard-of-care tumor analysis (some combination of histological analysis of tumor tissue samples or visual inspection or some other spectroscopic technique) had determined that the original tumor mass excision was sufficient to ensure absence of residual disease.

- More specifically, B-Series identified fifty-six residual disease margins in thirty-five distinct patients in the study, with residual disease found in fourteen of those patients & then fully clearing seven of those patients of all residual disease after the original tumor excision had concluded. In a separate analysis, patients for whom tumor margins were assessed with B-Series providing image data that allowed surgical oncologists to more precisely quantify the amount of residual tissue that needed to be removed to enhance the probability that all breast tumor tissue was indeed removed.

- 19.9% of tumor tissue still required follow-up shaving when margins were assessed with existing standard-of-care/visual inspection, as compared to only 3.8% of residual tissue in B-Series-assessed patients, presumably because B-Series margin assessment was more accurate & thus better able to improve surgical outcomes when compared to standard-of-care.

We commented at the time that this performance seemed to us to be sufficiently positive, especially when considering that Perimeter's first-generation not-yet-AI-enabled S-Series OCT platform was already FDA approved, to support B-Series approval & that prediction has turned out to be correct, mitigating risk to our existing revenue/EBITDA forecasts.

Exhibit 1. Financial Forecast Summary for Perimeter Medical Imaging

Year-end December 31 (US$000, exc per share data)	2024A	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E
OCT, capital equipment, US	0	1,050	3,188	4,148	5,286	6,608	8,439	10,635	11,251	11,881	12,692
OCT, capital equipment, EU	0	0	0	1,451	2,937	3,821	4,941	6,305	6,600	6,457	5,858
OCT, consumables, US	487	672	2,270	5,855	13,825	28,359	60,068	86,719	114,133	144,685	177,261
OCT, consumables, EU	0	0	52	764	3,220	7,620	15,188	22,782	32,574	45,112	60,817
Service/maintenance, US/EU	0	420	1,150	2,346	4,049	6,315	9,338	13,339	17,615	22,057	26,572
Operating leases	359	500	500	500	500	500	500	500	500	500	500
Total revenue	**846**	**2,642**	**7,159**	**15,063**	**29,817**	**53,223**	**98,474**	**140,280**	**182,674**	**230,693**	**283,700**
Revenue growth, y/y (%)	*110%*	*212%*	*171%*	*110%*	*98%*	*78%*	*85%*	*42%*	*30%*	*26%*	*23%*
Gross margin	**754**	**979**	**3,658**	**9,897**	**20,307**	**37,310**	**70,510**	**100,975**	**132,543**	**168,435**	**208,138**
Gross margin, capital equipment	*NA*	*NA*	*25.0%*	*40.0%*	*50.0%*	*50.0%*	*50.0%*	*50.0%*	*50.0%*	*50.0%*	*50.0%*
Gross margin, serv/maint, OCT (%)	*86.6%*	*89.2%*	*45.0%*	*60.0%*	*75.0%*	*75.0%*	*75.0%*	*75.0%*	*75.0%*	*75.0%*	*75.0%*
Operating costs, grant income	16,826	16,410	15,200	17,069	16,893	16,782	16,530	16,828	16,933	17,042	17,573
EBITDA	**(16,072)**	**(15,431)**	**(11,542)**	**(7,171)**	**3,414**	**20,528**	**53,980**	**84,147**	**115,609**	**151,393**	**190,565**
EBITDA margin (%)	*NA*	*NA*	*NA*	*NA*	*11%*	*39%*	*55%*	*60%*	*63%*	*66%*	*67%*
EBITDA growth, y/y (%)	*NA*	*NA*	*NA*	*NA*	*(148%)*	*501%*	*163%*	*56%*	*37%*	*31%*	*26%*
Net Income, fully-taxed	(13,394)	(14,681)	(10,792)	(6,421)	3,123	15,958	41,048	63,673	87,269	114,107	143,486
EPS (basic)	($0.14)	($0.11)	($0.08)	($0.05)	$0.02	$0.12	$0.31	$0.49	$0.67	$0.87	$1.09
EPS (fd)	**($0.11)**	**($0.08)**	**($0.06)**	**($0.04)**	**$0.02**	**$0.09**	**$0.24**	**$0.37**	**$0.50**	**$0.66**	**$0.83**
S/O (basic)	*93,514*	*131,121*	*131,121*	*131,121*	*131,121*	*131,121*	*131,121*	*131,121*	*131,121*	*131,121*	*131,121*
S/O (fd)	*118,442*	*193,655*	*173,898*	*173,898*	*173,898*	*173,898*	*173,898*	*173,898*	*173,898*	*173,898*	*173,898*
Units placed or sold, US/EU	*8*	*17*	*46*	*71*	*98*	*128*	*168*	*219*	*229*	*234*	*235*
Cumulative installed base	*11*	*28*	*74*	*145*	*243*	*371*	*539*	*758*	*987*	*1,221*	*1,456*
P/E	*NA*	*NA*	*NA*	*NA*	*17.8x*	*3.5x*	*1.4x*	*0.9x*	*0.6x*	*0.5x*	*0.4x*
EV/EBITDA (basic S/O)	*NA*	*NA*	*NA*	*NA*	*8.3x*	*1.4x*	*0.5x*	*0.3x*	*0.2x*	*0.2x*	*0.1x*

Source: Historic data – Perimeter Medical Imaging financial filings; Forecasts/Estimates – Leede Financial Inc.

There are other imaging platforms that have been tested for their clinical utility in breast tumor margin assessment but OCT-based techniques (of which B-Series is one) compares favorably in various peer-reviewed meta-analyses we have surveyed on this topic. One paper published in Sept/25 in the *European Journal of Surgical Oncology* by Baylor University researchers (including Perimeter collaborator AM Thompson) concluded that OCT -based technologies has published sensitivity that was at the top range of sensitivity published for other platforms, such as X-ray imaging, bioimpedance spectroscopy or mass spectroscopy.

Exhibit 2. Valuation Summary for Perimeter Medical Imaging

NPV, discount rate		10%	15%	20%	25%	30%	40%
Implied value per share		$10.35	$6.54	$4.21	**$2.42**	$1.83	$0.81
Price/earnings multiple, F2030	**P/E**	**10%**	**15%**	**20%**	**25%**	**30%**	**40%**
Implied share price[1]	10	$2.06	$1.72	$1.45	$1.23	$1.05	$0.78
	20	$4.12	$3.44	$2.90	**$2.42**	$2.10	$1.56
	30	$6.18	$5.16	$4.35	$3.69	$3.15	$2.34
EV/EBITDA multiple, F2030		**5x**	**7.5x**	**10x**	**12.5x**	**15x**	**17.5x**
Implied share price[1,2]		$0.64	$0.96	$1.28	**$1.59**	$1.91	$2.23
One-year Perimeter Medical target price [1,2]					**$2.14**		
One-year Perimeter Medical target price [1,2,3]					**$2.93**		

[1] *F2030 fully-taxed EPS (fd) forecast US$0.27, EBITDA US$53.9M; NPV discounted at 25%; fd S/O 154.1M*

[2] *Balance sheet data includes FQ325 cash of US$1.7M/C$8.5M, no LT debt; current basic S/O 111.4M*

[3] *Price target converted to USD using exchange rate of 1.37x*

Source: Leede Financial Inc.

Cytologic evaluation was the most sensitive/specific technology described for determining tumor margins in excised tumors & we are sure that Perimeter itself would not debate that conclusion, but cytology requires laboratory interpretation of immunohistochemically-stained samples that require pathology laboratory infrastructure & time for analysis that extends far beyond that required for B-Series real-time breast tumor margin assessment.

Summary & valuation. Our investment thesis & the financial forecasts on which it is based already assumed that B-Series (now branded as CLAIRE) would be FDA-approved based on our own assessment of clinical data described above & so our valuation is not materially altered by the event, notwithstanding its positive impact on B-Series business risk that is now substantially reduced by the approval. Accordingly, we are maintaining our Speculative Buy rating & one-year PT of $3.00 on PINK, with our valuation still based on NPV & multiples of our F2030 EBITDA/EPS forecasts as shown in Exhibits 1 & 2.

Exhibit 3. Consolidated Revenue Forecasts For Perimeter, Canada/US Medical Market, F2024A-to-F2032E

Fiscal year-end Dec 31 *(US$000, unless otherwise stated)*	*2024A*	*2025E*	*2026E*	*2027E*	*2028E*	*2029E*	*2030E*	*2031E*	*2032E*
B-Series AI OTC - US, localized breast cancer, capital equipment sales									
B-Series AI OCT (or S-Series) units sold	0	7	21	27	34	42	53	66	69
B-Series AI OCT units placed (no revenue)	8	10	20	27	36	49	66	89	93
B-Series AI OCT, price per system (US$)	$150,000	$150,000	$151,800	$153,622	$155,465	$157,331	$159,219	$161,129	$163,063
B-Series AI OCT, capital rev on sold systems, US (US$000) [5]	**$0**	**$1,050**	**$3,188**	**$4,148**	**$5,286**	**$6,608**	**$8,439**	**$10,635**	**$11,251**
B-Series AI OCT, cap rev, US (C$000)	$0	$1,451	$4,405	$5,732	$7,304	$9,131	$11,661	$14,696	$15,548
B-Series AI OTC - US, localized breast cancer, recurring revenue									
Proportion, estimated individuals diagnosed with breast cancer, US [1]	331,559	333,217	334,883	336,557	338,240	339,931	341,631	343,339	345,056
Proportion, early stage breast cancer [2]	205,567	206,594	207,627	208,666	209,709	210,757	211,811	212,870	213,935
Total annual procedures, amenable for breast conserving surgery (BCS) [3]	125,396	126,023	126,653	127,286	127,922	128,562	129,205	129,851	130,500
B-Series AI OCT market penetration (%)	*0.5%*	*0.7%*	*2.3%*	*5.9%*	*13.6%*	*27.2%*	*56.1%*	*79.1%*	*101.5%*
B-Series AI OCT, annual procedures per	59	32	43	61	90	123	180	184	184
Cumul installed base, US (see above)	11	28	69	123	193	284	403	558	720
Total B-Series AI OCT breast surgery procedures, annual, US	650	896	2,967	7,503	17,370	34,932	72,540	102,672	132,480
Assumed price per consumable per procedure (US$)	$750	$750	$765	$780	$796	$812	$828	$845	$862
B-Series AI OCT, procedure-based revenue on accessories, US (US$000)	**$487**	**$672**	**$2,270**	**$5,855**	**$13,825**	**$28,359**	**$60,068**	**$86,719**	**$114,133**
B-Series AI OCT, proc rev, US (C$000)	$673	$929	$3,137	$8,090	$19,105	$39,189	$83,007	$119,837	$157,721
Total B-Series AI OCT gross sales, US (US$000)	**$487**	**$1,722**	**$5,458**	**$10,002**	**$19,111**	**$34,967**	**$68,506**	**$97,354**	**$125,385**

[1,2] *American Cancer Society (https://www.cancer.org/cancer/types/breast-cancer/about/how-common-is-breast-cancer.html)*

[3] *CA: A Cancer Journal For Clinicians (2019). Vol. 69, pp. 438-451.*

[4] *ECIS - European Cancer Information System (https://ecis.jrc.ec.europa.eu/)*

[5] *Historic unit sales & procedure volumes to end-of-F2024 are for FDA-approved S-Series platform*

Source: Historic data – Perimeter Medical Imaging financial filings; Estimates/Forecasts - Leede Financial Inc.

Our PINK investment thesis is solely based now on B-Series commercial traction in approved markets, with minor contribution going forward from Perimeter's first-generation S-Series OCT-based imaging platform that is mechanistically similar to B-Series but without AI functionality. Our model assumes that US capital equipment & consumables sales in the breast reconstruction surgical market can ramp linearly during our forecast period, generating consolidated revenue of US$7.2M this year, increasing to US$15.1M in F2027 during which we expect CE Mark in Europe to be achieved by FH227. In our valuation reference year, F2030, we project consolidated revenue/EBITDA/Eps of US$98.4M/US$54.0M/US$0.24/shr, which we believe is achievable if B-Series can become standard-of-care as a real-time tumor margin assessing technology in this seminal surgical oncology medical market.

Our model projects that marketing expense can be kept low through direct relationships with US oncology medical centers without the need to reach out to the broader & more diffuse US hospital market. There is an abundance of medical literature that describes how real-time tumor margin assessment could be relevant in other surgical oncology markets, head & neck

cancers specifically but not exclusively, but for now our forecasts are based on S-Series/B-Series adoption in US/EU markets for localized breast cancer lumpectomy procedures.

Exhibit 4. Consolidated Revenue Forecasts For Perimeter, EU & Consolidated Medical Market, F2024A-to-F2032E

Fiscal year-end Dec 31 *(US$000, unless otherwise stated)*	*2024A*	*2025E*	*2026E*	*2027E*	*2028E*	*2029E*	*2030E*	*2031E*	*2032E*
B-Series AI OTC - EU-UK-Scandinavia, localized breast cancer, capital equipment sales									
B-Series AI OCT (or S-Series) units sold	0	0	0	7	14	18	23	29	30
B-Series AI OCT units placed (no revenue)	0	0	5	10	14	19	26	35	37
B-Series AI OCT, price per system (€)	€ 174,236	€ 174,236	€ 176,327	€ 178,443	€ 180,584	€ 182,751	€ 184,944	€ 187,164	€ 189,410
B-Series AI OCT, cap rev, US (€000)	€ 0	€ 0	€ 0	€ 1,249	€ 2,528	€ 3,290	€ 4,254	€ 5,428	€ 5,682
B-Series AI OCT, cap rev, EU (C$000)	$0	$0	$0	$1,984	$4,015	$5,224	$6,755	$8,619	$9,023
B-Series AI OCT, capital rev on sold systems, US (US$000) [5]	**$0**	**$0**	**$0**	**$1,451**	**$2,937**	**$3,821**	**$4,941**	**$6,305**	**$6,600**
B-Series AI OTC - EU-UK-Scandinavia, localized breast cancer, recurring revenue									
Proportion, estimated individuals diagnosed with breast cancer, EU [4]	451,858	454,118	456,388	458,670	460,963	463,268	465,585	467,913	470,252
Proportion, early stage breast cancer [2]	280,152	281,553	282,961	284,375	285,797	287,226	288,662	290,106	291,556
Total annual procedures, amenable for breast conserving surgery (BCS) [3]	170,893	171,747	172,606	173,469	174,336	175,208	176,084	176,965	177,849
B-Series AI OCT market penetration (%)	*0.0%*	*0.0%*	*0.0%*	*0.4%*	*1.7%*	*4.0%*	*7.7%*	*11.3%*	*15.8%*
B-Series AI OCT, annual procedures per	0	0	10	33	60	80	100	100	105
Cumul installed base, EU (see above)	0	0	5	22	50	87	136	200	267
Total B-Series AI OCT breast surgery procedures, annual, EU	0	0	50	726	3,000	6,960	13,600	20,000	28,035
Assumed price per consumable per procedure (€)	€ 871	€ 871	€ 888	€ 906	€ 924	€ 943	€ 961	€ 981	€ 1,000
B-Series AI OCT, proc rev, EU (€000)	€ 0	€ 0	€ 44	€ 658	€ 2,772	€ 6,560	€ 13,076	€ 19,613	€ 28,043
B-Series AI OCT, proc rev, EU (C$000)	$0	$0	$71	$1,044	$4,402	$10,418	$20,764	$31,146	$44,532
B-Series AI OCT, procedure-based revenue on accessories, US (US$000)	**$0**	**$0**	**$52**	**$764**	**$3,220**	**$7,620**	**$15,188**	**$22,782**	**$32,574**
Total B-Series AI OCT gross revenue, EU (US$000)	**$0**	**$0**	**$52**	**$2,215**	**$6,157**	**$11,441**	**$20,129**	**$29,087**	**$39,174**
Consolidated Revenue									
Capital sales, B-Series AI OCT	$0	$1,050	$3,188	$5,599	$8,222	$10,429	$13,380	$16,939	$17,852
Consumables, B-Series AI OCT	$487	$672	$2,321	$6,619	$17,045	$35,979	$75,256	$109,501	$146,707
Maintenance/service (10% of notional capital cost per annum)	$0	$420	$1,150	$2,346	$4,049	$6,315	$9,338	$13,339	$17,615
Operating lease revenue	$359	$500	$500	$500	$500	$500	$500	$500	$500
Total consolidated revenue (US$000)	**$846**	**$2,642**	**$7,159**	**$15,063**	**$29,817**	**$53,223**	**$98,474**	**$140,280**	**$182,674**

[1,2] *American Cancer Society (https://www.cancer.org/cancer/types/breast-cancer/about/how-common-is-breast-cancer.html)*
[3] *CA: A Cancer Journal For Clinicians (2019). Vol. 69, pp. 438-451.*
[4] *ECIS - European Cancer Information System (https://ecis.jrc.ec.europa.eu/)*
[5] *Historic unit sales & procedure volumes to end-of-F2024 are for FDA-approved S-Series platform*

Source: Historic data – Perimeter Medical Imaging financial filings; Estimates/Forecasts - Leede Financial Inc.

Competitive landscape includes a few innovative imaging modalities, but none yet with AI capabilities or that use optical coherence tomography imaging as the visualization platform. As we indicated above, current standard-of-care in breast tumor margin assessment is one or more of the following techniques: tumor palpation or visual inspection, X-ray radiography, ultrasound imaging, histopathology (cytological analysis of tissue at the margin of removed tumor lumps, stained with agents that bind to known breast cancer biomarkers), either alone or in some combination. However, there are alternative fluorescence- and MRI-based tumor margin-assessing technologies in clinical development that could alter competitive landscape in surgical treatment of localized breast cancer going forward. In an earlier PINK report, we summarized a few of these technologies as described in a 2022 review in the journal *Gland Surgery* & they include:

- **LUM Imaging System (fluoroscopy).** MA-based Lumicell's [private] developed a fluorescence-based direct visualization system that combines a cathepsin-cleavable PEGylated prodrug polymer pegulicianine called Lumilight) with its corresponding Lumicell Direct Visualization System (DVS), with the combination branded as the LUM Imaging System. The imaging agent-device combination was approved in April/24 & launched in Jan/25.

Exhibit 5. Comparable Companies For Perimeter Medical Imaging

Company	Curr	Sym	Shares out (M)	Share price 4-Mar	Mkt cap ($M) (curr)	Mkt cap ($M) (C$)	Ent val ($M) (curr)	Ent val ($M) (C$)	Status of lead program
Small-to-Mid Cap Medical Technology Development Peers									
Butterfly Network Inc	USD	BFLY	254.6	$3.68	937	$1,282	793	$1,084	Handheld, single-probe ultrasound system capable of scanning whole body and can plug into a smartphone
Nano-X Imaging Ltd	USD	NNOX	69.2	$2.59	179	$245	137	$188	Developer of the digital X-ray Nanox.ARC
Profound Medical Corp	USD	PROF	36.3	$7.28	264	$361	246	$337	Ultrasound ablation platform TULSA-PRO (prostate ablation); HIFU device Sonalleve (uterine fibroids)
VentriPoint Diagnostics Ltd	CAD	VPT	187.4	$0.11	20	$20	22	$22	AI-driven VMS 4.0 echocardiography platform; monitors right-side heart disease
Average						**$209**		**$182**	
Large Cap/Mature Medical Imaging Firms									
Hologic Inc	USD	HOLX	223.2	$75.46	16,846	$23,040	17,002	$23,253	Diversified medical imaging firm with breast health business segment providing breast imaging products; acquisition by Blackstone & TPG Capital is pending
Canon Inc	JPY	7751	878.6	¥4,495	¥3,949,419	$34,238	¥6,475,269	$56,134	Acquired Toshiba's medical systems business in 2016; name change to Canon Medical Systems Corp. in 2018
General Electric Co	USD	GE	1,048.8	$334.14	350,451	$479,311	358,774	$490,695	Medical imaging giant; sells handheld ultrasound devices for use in breast imaging
Integra Lifesciences Holdings Corp	USD	IART	77.9	$10.56	823	$1,126	2,415	$3,304	Diversified surgical/medical equip manufacturer (neursurgery, orthopedics)
Intuitive Surgical Inc	USD	ISRG	355.1	$497.42	176,649	$241,603	170,720	$233,494	da Vinci robotic surgery platform has been tested in breast surgery
Konica Minolta Inc	JPY	4902	494.2	¥525	¥259,489	$2,250	¥567,085	$4,916	JP-based imaging/printing giant, has a healthcare division in NJ
Koninklijke Philips NV	EUR	PHG	951.3	€ 25.69	€ 24,439	$38,809	€ 29,785	$47,299	Netherlands-based imaging/diagnostics firm
Onex Corp	USD	ONEX	76.2	$104.05	7,927	$10,842	6,842	$9,358	Onex's subsidiary Carestream Health is a provider of breast imaging equipment used for diagnostic use
Siemens AG	EUR	SIE	780.7	€ 226.45	€ 176,799	$280,757	€ 216,450	$343,723	Germany-based imaging/diagnostics firm; acquired Varian Medical for its TrueBeam RT platform in Aug/20
Siemens Healthineers AG	EUR	SHLG	1,128.0	€ 40.07	€ 45,199	$71,776	€ 57,313	$91,013	Germany-based MRI-PET-CT equipment manufacturer
Average						**$123,553**		**$134,686**	
Perimeter Medical Imaging AI Inc	**CAD**	**PINK**	**131.1**	**$0.32**	**$42**	**$42**	**$40**	**$40**	**Optical coherence tomography (OCT) imaging platform S-Series approved in Mar/21, AI-enabled B-Series approved in Mar/26**

Source: Company filings, Leede Financial Inc.

- Lumicell already has device-specific Category III CPT codes that were put in place back in early FQ324 (0945T), with the code describing use of intra-operative fluorescence imaging for margin assessment following breast cancer lumpectomy; in so doing, it does not overlap in any technological way with Perimeter's AI-enabled OCT platform. The technology is undergoing a distinct 66-patient Phase I/II esophageal-pancreatic-colorectal cancer surgery trial at Massachusetts General Hospital for which tumor margin accuracy data (comparing margin data to pathology data) are expected during FQ227.

- As we described in our last PINK report, Lumilight/DVS did perform reasonably well in a 230-patient study published by US-based researchers (the INSITE group) in 2022 in the journal *JAMA Surgery*, showing therein a Lumilight/DVS sensitivity of 69.4% that compared favorably with standard pathology assessment that was far less sensitive at 38.2%. There was a fairly high false-negative rate of 23.7%, but 19% of evaluable patients avoided the need for re-excision of tumor tissue, a modest but non-trivial proportion in our view.

- The technology is notionally similar to the indocyanine green-based fluorescence detection platform that legacy coverage stock ON-based Novadaq (now part of Stryker [SYK-NY, NR]) developed for assessing tissue vascularization post-surgery as either SPY or PINPOINT in a few surgical oncology markets, including in breast

surgery. Novadaq's T12M revenue at the time of its US$701M acquisition (so over the FQ216-to-FQ117 period) was US$77.2M. As a private firm, we do not have direct insight (no pun intended) into its early commercial traction, other than it announced an initial LUM Imaging System placement at Stanford University in Jan/25.

- Another fluorescence-based imaging platform that we are monitoring is based on multimodal optical microscopy & undergoing testing at the TX-based MD Anderson Cancer Center in collaboration with MD-based CRO Physical Sciences (private); feasibility data were published in 2021 in the journal *PLoS ONE*. Like pegulicianine in the LUM Imaging System, this alternative pro-drug platform is cleaved in the body not by capsaicin but by the enzyme urokinase. The fluorescent urokinase-cleavable contrast agent did perform well in a twenty-sample proof-of-concept trial & along with the LUM Imaging System, is forming the basis for incentivizing other fluorescence probe developers to explore other fluorescent pro-drugs that could be relevant in tumor margin analysis.
- Various firms are testing the well-known agent fluorescein & its analog BHQ3 as imaging agents when attached to mAbs that bind to well-characterized tumor-specific biomarkers like HER2. One study we are monitoring is the University of Groningen-based 70-patient MARGIN-2 trial that is evaluating the mAb-fluorescent probe conjugate bevacizumab-IRDye800DW (bevacizumab is Roche's [ROG-SW, NR] VEGF-targeted Avastin) for its ability to visualize residual tumor tissue after one-year post-lumpectomy surgery. The study is still recruiting patients but was expected to generate data in late F2024. Data from an earlier Phase I meningioma surgery trial (the LUMINA trial) were separately published in Jul/24 in the *Journal of Neurosurgery*, data that while not directly relevant to breast cancer surgery were validating for the safety profile of the drug when used intraoperatively.
- Another clinical study we are tracking is the 104-patient Spectra-BREAST trial testing the utility of hyperspectral imaging (HIS)-Raman spectroscopy as a breast tumor margin analysing platform. The study is being conducted at a single site in Italy, with sensitivity/specificity data as compared to histopathology analysis expected by end-of-F2028.

- VisionCT (X-ray). A high-resolution 2D specimen CT/mammography platform VisionCT was developed by AR-based Faxitron Bioptics, with the firm long ago acquired by MA-based Hologix [HOLX-Q, NR; itself about to be taken private by private equity firms Blackstone & TPG] in 2018 for US$85M. VisionCT was FDA-approved under the 510(k) regulatory pathway back in May/18. Hologic did not provide any VisionCT-specific revenue information in its most recent financial filings so we have no overt evidence of its pace of adoption in surgical oncology venues where we would expect Perimeter to focus its own marketing activities.
- ClearSight (magnetic resonance). the MRI-based ClearCoast MRI System as developed by Israel-based Clear-Cut Medical (private) and for which sensitivity/specificity were 0.80/0.84 as press-released by Clear-Cut in May/21 & published in early 2022 in the *Journal of Surgical Oncology*. Some earlier insights into ClearCoast's utility were a bit more impressive on sensitivity/specificity (91%/93%) as published by Israel-based collaborators in the same journal for a 77-sample Phase I/II study back in 2016.
- MarginProbe (RF energy). And lastly, handheld radiofrequency energy-based MarginProbe is being developed by VA-based Dilon Technologies [private], with a next-generation MarginProbe II device undergoing clinical testing in NY-based hospitals. The first patient was enrolled in the 398-patient trial in Feb/24 & data clearly was favorable since MarginProbe II was FDA-approved in Dec/25.
  - According to information provided by Dilon in the US NIH's clinical database, the primary endpoint of the MarginProbe II trial was actually adverse event rate during lumpectomy surgery & not reoperation rate or accuracy of tumor margin assessment, as was Perimeter's 206-patient breast tumor margin analysis trial on which B-Series approval was based. But that said, Dilon did report in its press release announcing MarginProbe II approval/launch in Dec/25 that the device was able to reduce re-operation rates in lumpectomy procedures by >54%, though this value is based on comparison to published re-operation rates & not to a standard-of-care control arm within the study itself. Sensitivity was >76%. We will watch for these data to be published in peer-reviewed form in coming quarters. The technology on which MarginProbe is based was in fact acquired by another Israel-based firm called Dune Medical back in Apr/20.

Disclosures None

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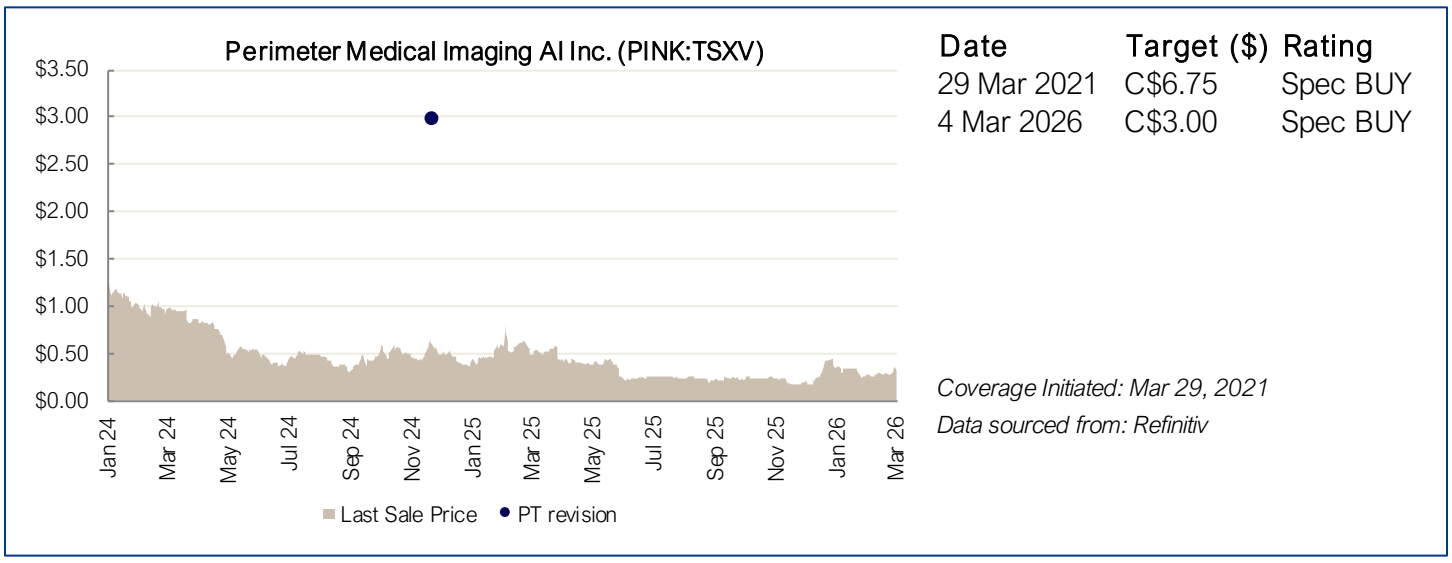
Buy	9	53%
Speculative Buy	5	29%
Hold	1	6%
Sell	-	-
Tender	1	6%
Under Review	1	6%

Historical Target Price



Date	Target ($)	Rating
29 Mar 2021	C$6.75	Spec BUY
4 Mar 2026	C$3.00	Spec BUY

Coverage Initiated: Mar 29, 2021

Data sourced from: Refinitiv