

EDAP TMS SA (EDAP)

Overweight

Initiating Coverage with an OW Rating and \$13 PT

CONCLUSION

We are initiating coverage of EDAP with an OW rating and \$13 PT. With reimbursement progress already having a positive effect on patient volumes and with EDAP management focusing investments on driving broad payer coverage in the U.S. and building a larger U.S. commercial presence, we believe we're on the cusp of seeing HIFU change how prostate cancer is managed. EDAP looks well positioned to capitalize on this trend, with a 20% sales growth profile for the company looking sustainable, in our opinion. As management executes on this HIFU strategy, we do believe the valuation gap that currently exists between EDAP and peers can narrow, and therefore recommend purchase of this stock.

- Opportunity to Change Prostate Cancer Management.** EDAP is devoting meaningful resources to market development and commercialization efforts for the use of High-Intensity Focused Ultrasound, or HIFU, in treating prostate cancer. We believe a combination of better patient outcomes and less burden on the healthcare system will contribute to a shift over time for how prostate cancer patients are treated.
- Reimbursement Key to Driving HIFU Utilization Higher.** Our conversations with Focal One users suggest the category 1 CPT code for HIFU that took effect at the beginning of '21 has already led to an inflection higher in Focal One utilization. This is encouraging real-world evidence that formalized reimbursement is truly driving a step change in how institutions are managing prostate cancer patients and a sign that hospitals interested in HIFU may now more easily justify the economic payback in purchasing a unit.
- Disrupting Standard of Care Isn't Easy or Cheap.** The prostate cancer market already has well-established protocols and disease management regimens in place, and hospitals have equipment installed such as robotic surgery systems and linacs to treat prostate cancer. It therefore won't be an easy feat convincing hospitals to acquire additional capital equipment to treat prostate cancer, especially without widespread payer coverage in place. There's also no guarantee EDAP's strategy to drive payer coverage, physician education, and overall market development will generate the desired commercial effect and returns for shareholders.
- Stock Thoughts and Valuation.** We see the clinical and medico-economic factors of HIFU use in prostate cancer as overcoming the above challenges, with growing adoption of HIFU systems the key factor positioning EDAP to be a ~20% top-line grower the next few years. As that growth profile becomes better appreciated, we believe shares of EDAP can close the two point sales multiple gap that currently exists between it and peers. Specifically, we're using a ~5x multiple (in line with peers) to arrive at our \$13 PT.

RISKS TO ACHIEVEMENT OF PT & RECOMMENDATION

Hospital capex budgets, well-established SOC in prostate cancer, securing payer coverage

COMPANY DESCRIPTION

EDAP TMS develops and manufactures minimally invasive devices utilizing ultrasound technology for various applications such as prostate cancer and kidney stones.

PRICE: US\$7.33

TARGET: US\$13.00

~5x EV/NTM+1 Sales of \$75M (assumes net cash of \$46M and 34.4M sharecount)

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Changes	Previous	Current
Rating		Overweight
Price Tgt		US\$13.00
FY21E Rev (mil)	—	US\$60.3
FY22E Rev (mil)	—	US\$72.3
FY21E EPS	—	US\$0.06
FY22E EPS	—	US\$0.15
52-Week High / Low	US\$10.68 / US\$2.00	
Shares Out (mil)		34.4
Market Cap. (mil)		US\$252.2
Avg Daily Vol (000)		297
Div Yield		0.00%
Fiscal Year End		Dec

Price Performance - 1 Year



Source: Bloomberg

YEAR	REVENUE (US\$ m)						EARNINGS PER SHARE (US\$)					
	Mar	Jun	Sep	Dec	FY	FY RM	Mar	Jun	Sep	Dec	FY	FY P/E
2020A	8.4	10.3	11.2	18.3	47.8	5.3x	(0.05)	(0.01)	(0.04)	0.03	(0.07)	NM
2021E	12.3	13.9	13.8	20.3	60.3	4.2x	(0.02)	0.00	0.00	0.07	0.06	NM
2022E	14.6	16.7	16.7	24.4	72.3	3.5x	(0.01)	0.02	0.02	0.11	0.15	48.9x

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**Investment Thesis**

**Potential to Change how Prostate Cancer is Managed.** EDAP has developed and commercialized a novel technology platform leveraging High-Intensity Focused Ultrasound, or HIFU. Through this technology platform, hospitals and physicians have an option to treat prostate cancer patients with a minimally invasive, gland preserving approach that has fewer side effects compared to current standard of care (robotic prostatectomy or radiotherapy). Considering this more favorable side effect profile and with treatment delivered in an outpatient setting (rather than requiring multiple days in a hospital to recover, or multiple treatment visits for a course of radiotherapy), the overall quality of life for patients receiving HIFU is also better. We believe the combined dynamic of these factors – better outcomes and QOL for patients and less burden on the healthcare system – will ultimately drive a change in how urologists manage prostate cancer patients over time.

**Reimbursement Code Driving a Step Change in Utilization, Should Lead to Solid New System Demand.** CMS recently finalized a category 1 CPT code to reimburse for the use of HIFU in treating prostate cancer, a move that already appears to be driving increased patient volumes into existing institutions with HIFU technology. Our Focal One user checks suggest monthly patient volumes are tracking 2-4x compared to 2019 and 2020 monthly patient volumes, an early indicator to us that the presence of formalized reimbursement is truly driving a change in how institutions are choosing to manage their prostate cancer patients, and a likely sign that hospitals interested in HIFU technology can now more easily justify the economic payback in purchasing a unit.

**Limited Direct Competition in Therapeutic Ultrasound.** EDAP is the lone player devoting significant attention to focused ultrasound therapy in treating prostate cancer. Privately-held SonaCare has an offering (Sonablate), but our checks suggest the company hasn't dedicated meaningful resources to the platform in recent years, and the system is inferior to that of EDAP's Focal One with respect to ease of use. Profound Medical (PROF, not covered) also has an offering with a different entry approach (transurethral) and mechanism of action (thermal ablation), but there are limitations for the therapy to reach the outer portion of the prostate where a majority of prostate cancers lie. In that limited competitive field, EDAP is left as the clear leader that continues to devote resources to developing HIFU as a new prostate cancer management tool, and we suspect that should be realized near and long term in EDAP capturing a majority of incremental HIFU-related procedure and revenue share.

**Longer-Term Opportunities for Indication Expansion.** EDAP is currently evaluating the use of HIFU to treat additional diseases, with a near-term focus on rectal endometriosis. Specifically for that indication, the company completed a feasibility study in 2019 and just six months ago began enrolling patients in a phase 2 study to confirm safety and efficacy. Our conversations with management indicate the results from this trial may be sufficient to secure CE Mark and/or FDA approval (although an IDE study in the U.S. may still be possible), which would expand the utility of the current Focal One system. We could envision this indication expansion could create an even stronger ROI argument for hospitals and help further expand the Focal One install base over time.

**Establishing \$13 Price Target.** Today we are initiating coverage on shares of EDAP with an Overweight rating and are establishing a \$13 price target. This price target is based on a multiple of just over 5x applied to our EV/NTM+1 revenue projection of \$75M, a couple point premium to EDAP's historical averages and roughly in line with other higher-growth, small-cap medtech peers. We see the premium to historical averages as warranted by the Medicare reimbursement rates that went into effect for HIFU at the beginning of this calendar year and which we expect will have positive implications on both the utilization of the existing install base and new system purchase discussions with hospitals. Compared to peers, the in-line multiple is reasonable when we consider the ~20% top-line growth potential and solid GM% expansion path for EDAP over the coming years in light of the HIFU points above, and we suspect evidence of progress in securing broad reimbursement

coverage and expanding the Focal One customer base will ultimately translate into a narrowing of the valuation gap that currently exists between EDAP and its small cap growth peers.

## Investment Risks

**Several Well-Established Technologies and Therapies to Currently Manage and Treat Prostate Cancer.** As the most common cancer among men, there are well-established protocols and disease management regimens in place for men diagnosed with prostate cancer. That includes both active surveillance of the cancer (no direct intervention), as well as other commonly used tools such as radiotherapy and minimally invasive prostatectomy. Each of these approaches have generally proven effective, and although each have their drawbacks, their established presence in disease management combined with the revenue generated for institutions, treating patients with radiotherapy or surgery makes disrupting this market no simple feat. We suspect meaningful resources, physician and patient education, and influence from major payers will be required to shift HIFU into being a mainstream care alternative for men with prostate cancer.

**U.S. Commercial Reimbursement for Focal One Not Yet in Place.** Despite the positive noted above regarding CMS reimbursement having been effective at the start of this year, EDAP must now turn its attention to securing coverage from the numerous private commercial payers in the U.S., particularly given that ~40% of new prostate cancer cases are in men that haven't yet reached Medicare age. While we're confident this is an effort that will be more a matter of "when" than "if", especially considering EDAP has engaged leading reimbursement consultant agencies in recent weeks to assist with the effort, the lack of formal coverage in place across commercial insurers could keep some institutions on the sidelines before moving forward with purchasing a Focal One unit.

**ESWL Segment Provides Limited Growth.** EDAP has an install base of over 700 lithotripsy devices across the globe and will continue to support this install base moving forward, but the company is strategically shifting its focus and resources towards the large opportunities available in HIFU. We view this as the right strategic decision, but it's worth keeping in mind that ESWL does account for roughly a third of EDAP's revenue and looks unlikely to contribute much growth for the overall company going forward.

## Stock Thoughts and Valuation

We are initiating coverage today with an Overweight rating on shares of EDAP and are establishing a \$13 price target, which represents a multiple of ~5x EV/Sales on our NTM+1 revenue projection of \$75M and more than 75% upside from yesterday's closing price of \$7.33. With EDAP operating near breakeven from an EBITDA and EPS standpoint, a multiple-based valuation approach must be one based on sales in our view. For comparison purposes, this ~5x EV/Sales multiple is roughly in line with the average and median of the peer group we've compiled below that we believe have similar characteristics to that of EDAP (disruptive technologies with opportunities for strong double digit growth over at least the next few years, smaller cap size at present). We believe a premium valuation could certainly be warranted if Focal One sales inflect higher as we believe they might, but we'd also like to see further evidence of this type of demand and/or progress in securing commercial payer coverage for HIFU before arguing for a premium valuation just yet.

Exhibit 1

**EDAP Peer Group Valuation Comparison**

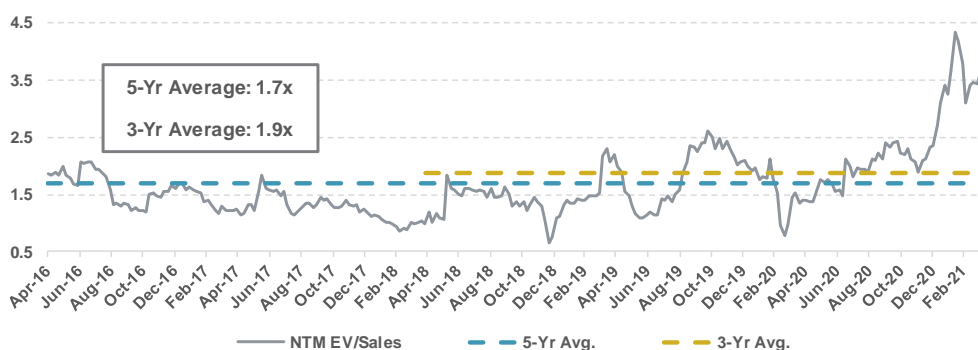
Name	Ticker	Price	Market Cap.	Consensus (mil)		EV/Sales	
				22E Rev.	23E Rev.	'22E	'23E
Vapotherm, Inc.	VAPO	\$21.60	\$557	\$99	\$114	4.5x	3.9x
Accuray Incorporated	ARAY	\$5.32	\$494	\$421	\$451	1.4x	1.3x
iCAD, Inc.	ICAD	\$18.25	\$455	\$51	\$61	7.6x	6.4x
Profound Medical Corp	PROF	\$18.79	\$383	\$32	\$59	8.6x	4.6x
Apyx Medical Corporation	APYX	\$10.08	\$346	\$54	\$79	5.6x	3.9x
IRadimed Corp.	IRMD	\$26.67	\$328	\$45	NM	6.3x	NM
Beyond Air, Inc.	XAIR	\$5.47	\$112	\$33	\$99	2.4x	0.8x
Average			\$382	\$105	\$144	5.2x	3.5x
Median			\$383	\$51	\$89	5.6x	3.9x
EDAP TMS SA Sponsored ADR	EDAP	\$7.33	\$214	\$77	\$103	2.6x	1.9x

Sources: Company Reports, FactSet (prices as of 4/27/2021), Piper Sandler Estimates

When looking at how this name has historically traded, the ~5x multiple we are using to value shares is a ~3-3.5 point premium to the stock's three- and five-year average trading levels. While market multiples are broadly higher today than at any point than the last several years, we'd argue the primary factor justifying a much higher multiple for shares of EDAP lies in the commercial inflection that we see for HIFU in the U.S. as the reimbursement structure becomes better established for the treatment. As we highlighted above, we see reimbursement as the necessary factor to stimulate change in how prostate cancer patients are managed in U.S. hospitals, and with broad coverage seeming to be a likely eventual outcome, in our opinion, we therefore see the financial profile of EDAP ultimately inflecting higher over time as a result.

Exhibit 2

**EDAP Historical EV/NTM Sales Valuation**



Sources: Company Reports, FactSet, Piper Sandler Estimates

**Company Background**






EDAP TMS was founded in 1979 with a focus on developing and introducing minimally invasive technologies to treat urological conditions and diseases. Product development originally began with the production of piezo-electric lithotripters in 1985 to treat kidney stones. EDAP merged with Technomed International in 1994, with the combined entity then launching several subsequent lithotripsy, laser, and microwave therapy devices, as well as developing HIFU (high-intensity focused ultrasound) to treat prostate cancer. The company is headquartered in Lyon, France, and maintains subsidiaries in the U.S., Germany, Japan, South Korea, and Malaysia, as well as two representative offices in Russia and UAE.

Today, EDAP's key product is the Focal One HIFU device to treat prostate cancer, which we expect to be the main driver of incremental growth for EDAP in the near to intermediate term. EDAP also has an ESWL business to treat kidney stones, with the key product for that segment being the

Sonolith i-move. Lastly, EDAP’s Distribution business encompasses a number of complementary products to its HIFU and ESWL businesses, including products from Exact Imaging, Quanta System, Lumenis, and Laborie. We provide a brief overview of each of EDAP’s businesses in the pages that follow.

Exhibit 3

**EDAP’s Product Portfolio**

HIFU Division		ESWL Division		DISTRIBUTION Division		
Manufactured by EDAP TMS		Distributed by EDAP TMS				
Non-Invasive HIFU treatment for Prostate Cancer and HIFU developments on other pathologies		Urinary Stones (ESWL) Non-Invasive treatment for Urinary Stones		Prostate Cancer Micro-Ultrasound Diagnostics	BPH and Lithiasis Holmium and Thulium Lasers for vaporization / Enucleation of Prostate and Urinary Stones	Urodynamics UroFlow / PressureFlow and Filling Cystometry
						

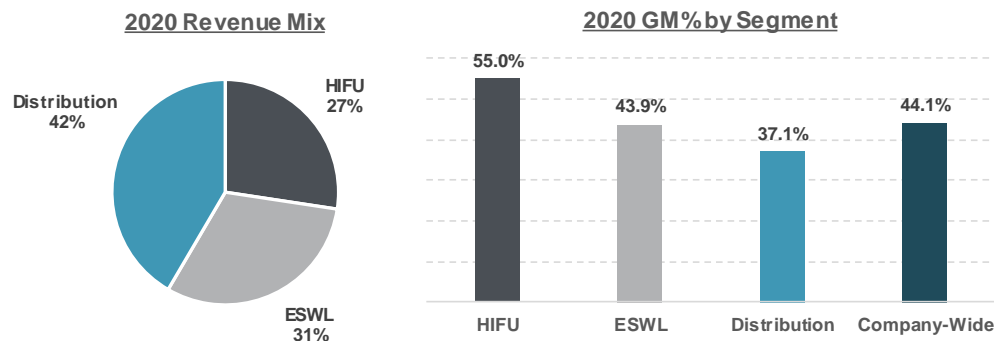
Sources: Company Reports

**Segment Review and Product Offering**

EDAP operates through three primary reporting divisions – HIFU, ESWL, and Distribution. We review each of these in greater detail below, but note here that revenue across the three divisions is currently fairly balanced, even though HIFU is positioned to be the dominant source of incremental growth for the company over the coming years. That dynamic should also have positive mix implications from a GM% perspective, with HIFU providing the strongest GM% profile of the three divisions, and we’d suspect there’s room for that HIFU-specific GM% to also move higher as volume scales and overhead is better leveraged.

Exhibit 4

**EDAP Revenue Mix & Gross Margin Profile**



Source: Company Reports, Piper Sandler Estimates

**Beginning with HIFU**, this business segment is comprised of the development and commercialization of robotic medical devices leveraging HIFU technology for the treatment of urological conditions. Specifically, EDAP’s HIFU systems are used in a minimally invasive fashion to ablate tumors using a high-intensity convergent ultrasound beam, and EDAP’s Focal One system also allows for the therapy to be delivered in a focalized manner to limit damage to surround tissues

and organs. At present, the company markets HIFU to treat localized prostate cancer, but also is actively developing a pipeline of additional indications to which HIFU technology could be applied, including rectal endometriosis, liver cancer, and pancreatic cancer.

The company currently has three HIFU systems – Ablatherm, Ablatherm Fusion, and Focal One – with the most recently approved Focal One (510(k) in June 2018) the system the company will likely lead with in most selling discussions with U.S. hospitals. As of the end of 2020, the company had an active install base of a total of 122 HIFU devices, 61 of which are Focal One systems.

Exhibit 5

**HIFU and Focal One Already Boast an Established Global Presence**

**EDAP'S FOCAL ONE SYSTEM**



122 HIFU installs, including 61 Focal One units

**EDAP's Top Five Markets for HIFU Installs**

1. United States
2. France
3. Germany
4. Italy
5. Taiwan

Source: Company Reports

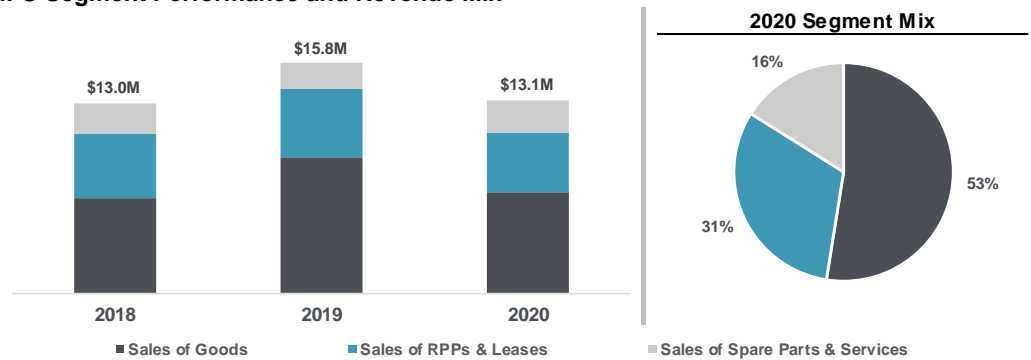
The company’s HIFU solution generates revenue through a few key areas, including a traditional razor/razor blade offering. Beginning with the razor, the company sells the HIFU units to institutions for a one-time capital sale of approximately ~\$650k (Focal One ASP; Ablatherm carries a lower ASP), with hospitals at this point commonly acquiring just a single system to accommodate their prostate patient volumes. There are then two separate recurring revenue elements following system sales: 1) ~\$60k-\$80k annual service contracts customers will purchase for their Focal One systems (price depends on geography, high stick rate and a well-accepted dynamic within the hospital capex landscape), and 2) FocalPak single-use disposables that are used in each HIFU procedure. From a reporting standpoint and as we show below, the company reports “Sales of Goods” (inclusive of sales of systems and disposables), “Sales of RPPs & Leases” (system revenue recognized on a revenue-per-procedure basis), and “Sales of Spare Parts & Services” (revenue from service contracts and parts sold for system repairs).

As for recent financial performance within HIFU, we show below recent trends regarding segment performance and the sub-segment revenue mix for 2020. To add some color, HIFU revenue did fall 19% to €11.4M (\$13.1M) in 2020 due to pressures from the pandemic on both capital equipment sales and procedure volumes. As for system sales specifically, EDAP sold 12 HIFU units last year (10 Focal One, 2 Ablatherm), down vs. 13 sold in 2019 (11 Focal One, 2 Ablatherm).



Exhibit 6

**HIFU Segment Performance and Revenue Mix**



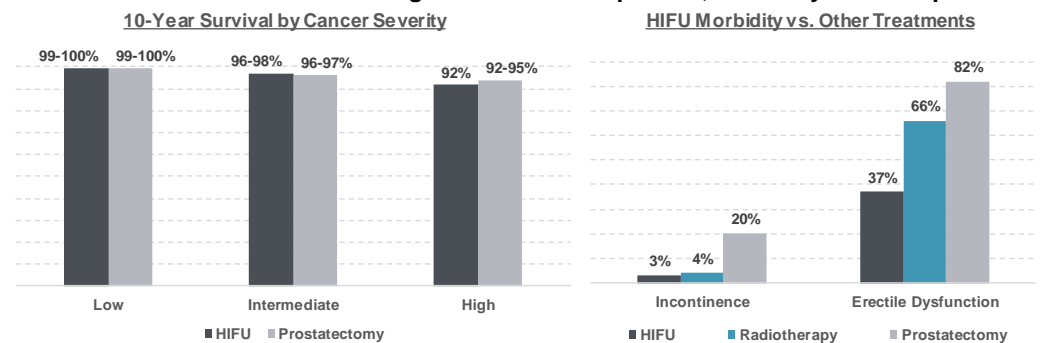
2018 EUR/USD rate = \$1.1784, 2019 EUR/USD rate = \$1.1184, 2020 EUR/USD rate = \$1.1474

Source: Company Reports, Piper Sandler Estimates

As far as clinical data for HIFU goes, there have been a number of studies assessing HIFU which have demonstrated average long-term survival to be in line with survival rates of prostatectomy in the high-90% range at ten years for low and intermediate cancer severities and the low-90% range for high severity. With respect to a morbidity comparison, HIFU has also been shown to have results superior to that of radiotherapy (RT) and prostatectomy, including rates of incontinence of 3% for HIFU two years after the procedure (vs. 4% for RT and 20% for prostatectomy) and erectile dysfunction of 37% two years post HIFU therapy (vs. 66% for RT and 82% for prostatectomy). It's for these clinical reasons, along with HIFU procedures being performed in a single outpatient setting (no costly overnight stay in a hospital, reduced risk of complications as compared to a surgical procedure, no need for multiple visits as is the case with a course of radiotherapy) that we believe will result in HIFU resonating with payers.

Exhibit 7

**HIFU vs. Current Treatment Offerings – Survival Comparable, Morbidity Rates Superior**



Source: FDA, Donovan et al N Engl J Med. 2016 Oct 13;375(15):1425-1437, Boorjian et al J Urol. 2008;179(4):1354-60, Stephenson et al J Clin Oncol. 2009 10;27(26):4300-5, Ganzer R, BJU Int. 2013;112(3):322-9, Thüroff S, J Urol. 2013;190(2):702-10, Crouzet S. Eur Urol. 2014;65(5):907-14

**Looking to the ESWL division**, this part of the business produces and markets lithotripters to treat urinary tract stones via extracorporeal shockwaves to fragment the stones and thereby allow them to be eliminated naturally. EDAP's ESWL division currently only sells one lithotripter model, the Sonolith i-move lithotripter, along with disposable parts that are typically replaced every ten treatments. The ESWL division's lithotripter installed base sat at 731 as of the end of 2020, which includes the Sonolith i-move and all of EDAP's previously sold lithotripter models.

Exhibit 8

**Sonolith i-move Lithotripter**

**EDAP'S SONOLITH I-MOVE SYSTEM**



Sold to small and mid-size hospitals and offered in a wide range of configurations to suit various budget and market needs

Cleared and available in U.S., UK, EU, Saudi Arabia, Colombia, South Korea, Costa Rica, Egypt, Indonesia, Japan, Malaysia, Philippines, Russia, Serbia, Switzerland, Taiwan, Ukraine, and Vietnam

One granted patent in U.S., four granted patents in EU, one granted patent in Japan

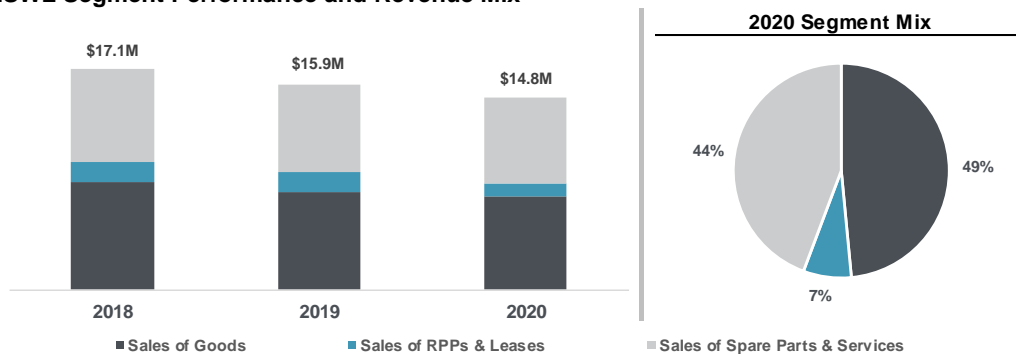
Source: Company Reports

From a revenue perspective, the ESWL division generated just under €13M (\$14.8M) in 2020, down ~9% y/y largely due to COVID-19 pressures on both procedure volume and equipment sales. Regarding the latter point, devices sold did actually increase by 5 to 33 total units, but sales fell 5% to €5.2M (\$6.0M) due to the mix of sales and likely at least some competitive-related ASP pressures.

As for the revenue mix in the ESWL segment, we show below that “Sales of Goods” (reminder, includes device and consumables sales) accounts for nearly half (49%) of ESWL revenue, while replacement parts and service contracts account for a bulk of the remaining revenue (44%). Other lithotripter purchase arrangements such as RPPs and leases represent the remaining piece of ESWL revenue (7%).

Exhibit 9

**ESWL Segment Performance and Revenue Mix**



2018 EUR/USD rate = \$1.1784, 2019 EUR/USD rate = \$1.1184, 2020 EUR/USD rate = \$1.1474

Source: Company Reports, Piper Sandler Estimates

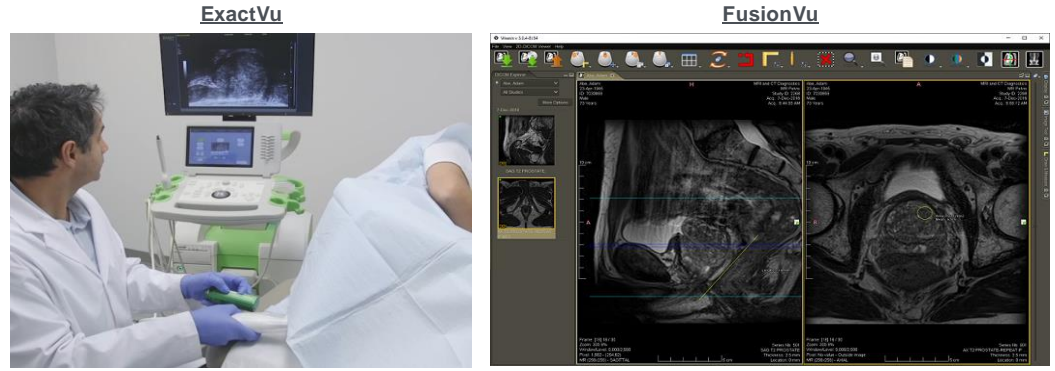
**Finally, EDAP also identifies its Distribution business as a reportable segment**, which includes products that are complementary to EDAP’s other global businesses, such as lasers, micro-ultrasound systems, and other third party medical products. Last year (May 2020), EDAP signed an exclusive worldwide distribution agreement with Exact Imaging which develops high resolution micro-ultrasound imaging technologies. Under this agreement, EDAP markets Exact’s ExactVu micro-ultrasound diagnostic devices alongside its Focal One HIFU technology to offer urologists a complete end-to-end solution for focal prostate cancer management. Specifically, ExactVu serves as strong diagnostic solution that allows urologists to visualize regions in the prostate that may require treatment and target biopsies in real time. If an MRI is required, Exact Imaging’s FusionVu



allows MRI images to be quickly imported so the physician can then precisely and in real time target the lesions.

Exhibit 10

Key Products from Exact Imaging



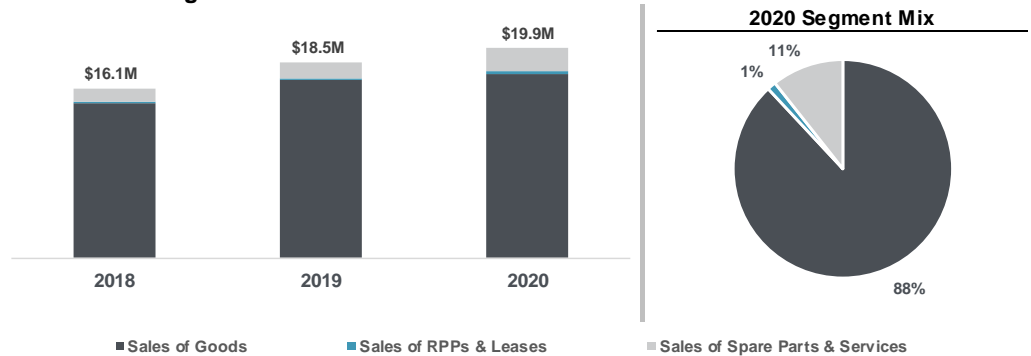
Source: Company Reports

Aside from Exact Imaging, EDAP also has agreements with various other manufacturers, including Lumenis' Holmium lasers (HoLEP), as well as lasers by Italian company Quanta System in Japan, certain countries in Southeast Asia, and certain territories in the Middle East. Additionally, EDAP is the exclusive distributor in Japan for some urology products from Canada-based Laborie Medical Technologies.

With respect to segment performance, EDAP's Distribution business generated €17.3M (\$19.9M) in revenue in 2020, a ~4% y/y improvement from 2019 largely due to incremental contributions from the Exact Imaging relationship. By sub-segment, medical device sales declined about 3% in 2020 to €10.6M (\$12.2M) which was offset by a ~19% increase to €6.8M (\$7.8M) in consumables, spare parts, supplies, RPP, and leasing and services.

Exhibit 11

Distribution Segment Performance and Revenue Mix



2018 EUR/USD rate = \$1.1784, 2019 EUR/USD rate = \$1.1184, 2020 EUR/USD rate = \$1.1474

Source: Company Reports, Piper Sandler Estimates

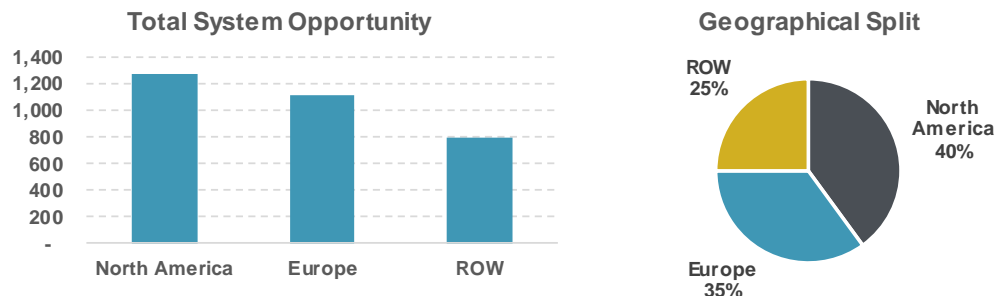
Market Opportunity for Focal One

On a global basis, management estimates the market opportunity for Focal One units to be approximately 3,200 systems. By geography, North America represents the largest single opportunity at just over 40% of the worldwide opportunity, Europe represents roughly 35% of the install opportunity, and Rest of World accounts for the remaining ~25% stub. To put this opportunity into numbers, we assume that the average Focal One system will carry a 10-year life, meaning

there's roughly \$200M in annualized revenue potential from Focal One system sales alone (320 systems per year at \$650k sales price).

Exhibit 12

**Estimated Install Opportunity for Focal One by Geography**



Source: Company Reports, Piper Sandler Estimates

Extending this logic to the service side of the equation, applying the ~3,200 Focal One TAM outlined above and assuming a blended service contract rate in the \$70k neighborhood (~\$80k/yr in the U.S., ~\$60k/yr int'l) to account for the install base geographic mix potential, we see the service business as representing a similar \$200M revenue opportunity (assumes 100% contract acceptance across all installs). Lastly on Disposables, this is another recurring revenue stream business that is a function of the number of patients treated with the system, and we assume FocalPak Disposables are priced at ~\$1,200 each in the U.S. and ~\$1,000 each in international markets. If we assume ~50 procedures per year are performed on each installed system, this represents roughly another \$175M market opportunity. In total, we see a pathway for an annual TAM of approximately \$600M, inclusive of systems + service + disposables.

From a competitive standpoint and as we noted earlier, the landscape of players leveraging ultrasound therapy to treat prostate cancer is fairly limited, with EDAP the main company devoting significant resources to develop the market. However, there are two other players worth highlighting in this discussion – privately-held SonaCare and Profound Medical (PROF, not covered). First on SonaCare, the company does have a HIFU offering called Sonablate with a similar therapeutic approach (utilizes minimally invasive focused ultrasound to deliver precise ablative energy to the prostate). Our checks on SonaCare's Sonablate, though, suggest the company hasn't been innovating to improve its HIFU offering, leaving the user experience with Sonablate inferior and more cumbersome relative to EDAP's Focal One. With respect to Profound Medical, the company provides a competitive minimally invasive treatment alternative to HIFU with its TULSA-PRO (Transurethral UltraSound Ablation), which requires a different procedural approach (transurethral vs. EDAP and SonaCare's transrectal). It's this different approach that our checks suggest limits the applicability of the therapy relative to a solution such as Focal One that can treat prostate locations where a vast majority of prostate cancers lie.

**P&L Review and Outlook**

As we unpack in the sections that follow, we see EDAP as being a strong double digit grower with GM% climbing higher towards and above 50% over the next few years, supported by the implications we see for EDAP's HIFU franchise following the category 1 CPT code made effective in January, minimal competitive threats to Focal One, EDAP's market development plans to accelerate uptake of HIFU in the U.S., and a pipeline of additional indications for EDAP to treat with HIFU.

Note that EDAP reports its financials in euros, but the company in many cases also provides converted values to dollars, so for the purpose of our analysis we will show values in USD according

to management’s foreign currency conversions or will make our own estimated conversions where those conversions have not already been made.

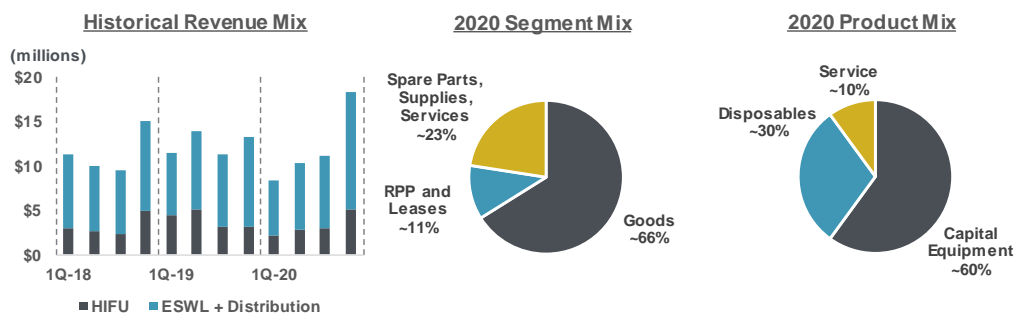
Revenue

Total company revenue at EDAP was growing at a high-single digit CAGR in the years leading up to the pandemic, and even despite pressures from COVID in 2020, the company still managed to deliver revenue not too far off 2019 levels. Specifically, 2020 revenue for EDAP declined ~7% y/y to \$47.8M (vs. \$50.2M in 2019), though 4Q saw impressive growth of 28% aided by ~51% growth in HIFU during the period. The ESWL and Distribution segments were also solid, growing collectively 14% vs. 4Q-19.

Despite this recent strength in the HIFU platform, the segment still represents just under 30% of company-wide revenue (see chart below on the left). Looking at company-wide revenue by the other means in which revenue is segmented, we show in the second chart below that approximately 2/3 of sales come from the sale of goods (i.e. systems and disposables), while “spare parts supplies, and services” and “RPP and leases” account for the other third of revenue. Finally, although management doesn’t provide these figures directly, we estimate from details in EDAP’s filings that capital equipment sales accounted for ~60% of the company’s revenue mix in 2020, with disposables closer to ~30% of sales and service accounting for the remaining ~10%.

Exhibit 13

**EDAP Historical Revenue Performance and Mix**

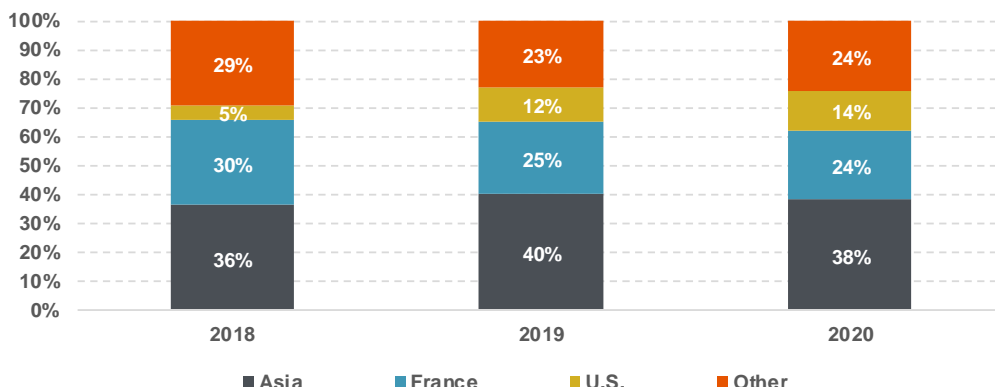


Sources: Company Reports, Piper Sandler Estimates

From a geographic perspective, we show below EDAP’s mix of revenues across its four reporting geographies, including Asia (~38% of 2020 revenue), France (~24%), U.S. (~14%), and Other (~24%). While the U.S. has historically represented a smaller piece of EDAP’s overall business, we’d expect the recent reimbursement progress and focus from management on further payer and commercial progress in the U.S. should translate to company-wide revenue mix shifting increasingly towards the U.S. over the next 3-5 years.

Exhibit 14

**EDAP Geographical Mix Past Three Years**



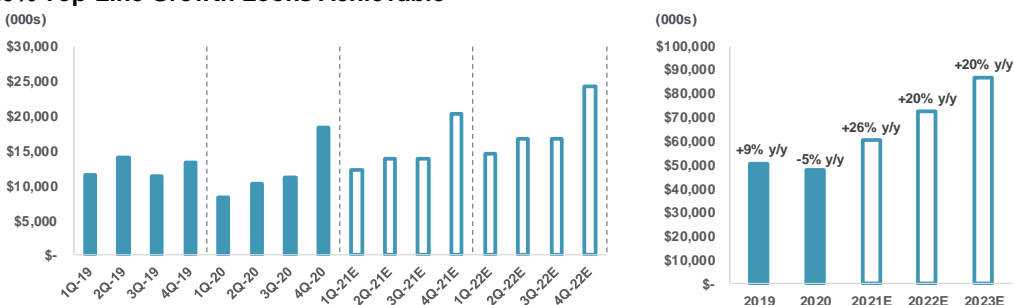
Sources: Company Reports

As for recent results and looking ahead to the balance of 2021, management did pre-announce 1Q revenue in conjunction with the company’s recent capital raise, with revenue for the quarter expected to be €10.0-€10.4M (~\$12.0-\$12.5M), growth of +32-37% y/y against a period in 1Q-20 that saw procedure volumes and system sales negatively impacted by COVID. For 1Q-21, management pointed to strength in the Distribution segment as the primary contributor to growth in the first three months of the year.

As for our projections beyond 1Q, we expect recent momentum in the Distribution segment to continue, although we also anticipate progress to be made in selling HIFU systems, particularly as stronger patient volumes in response to the category 1 CPT code now in place should stimulate a greater number of Focal One purchase discussions with hospitals. We also anticipate an easing of COVID concerns in the U.S. over the course of the year should allow hospitals to allocate resources and investments back to areas like oncology that may have been deferred over the past year. As we look at the next three years for EDAP and show in the charts below, we’re projecting revenue of \$60M/+26%, \$72M/+20%, and \$87M/+20%, respectively.

Exhibit 15

**20% Top-Line Growth Looks Achievable**



Sources: Company Reports, Piper Sandler Estimates

**Profitability**

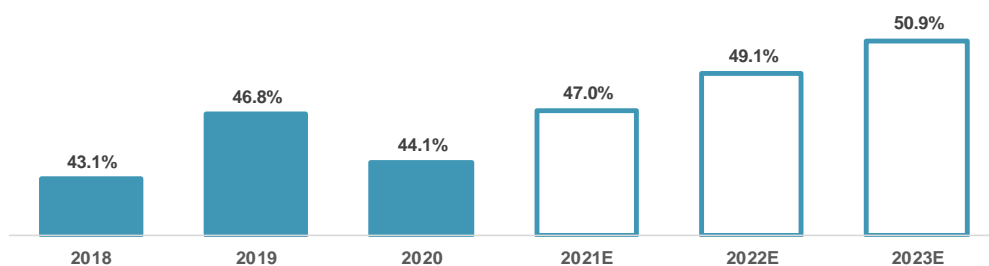
Turning to profitability, GM% for EDAP has trended in the low- to mid-40% range in recent years, with 2019 representing the recent peak when GM% nearly touched 47%. But COVID-19 volume and demand pressures in HIFU led to a mix shift away from the higher-margin franchise, with company-wide GM% contracting 270bp to 44.1%.

As for recent trends, EDAP did finish 2020 on a high note with GM% finishing above the full-year level at 45.8%, supported by the stronger year-end HIFU demand referenced earlier. Management also did point in its recent pre-announcement to 1Q GM% that's likely to finish in a range of 40-44%, and while this is a modest sequential deceleration (likely mix-related considering strength in the quarter was supported by the lower-margin Distribution arm), it does represent a ~180bp y/y expansion at the midpoint.

Looking beyond 1Q, we do expect EDAP's gross margin profile to show sequential improvement through the rest of the year, as well as year-to-year gains in 2022 and 2023. Keeping with the theme discussed throughout this note, we anticipate these improvements in profitability to be largely tied to revenue progress made in the higher-margin HIFU business, as well as scale and production efficiency advantages that should further accrue to the company over time. For our model specifically, we're projecting GM% in 2021 will reach 47.0% (+290bp y/y and slightly above 2019 levels), followed by roughly ~200bp of annual GM% expansion in the following two years that support a move in GM% to nearly 51% by 2023.

Exhibit 16

**Approximately 200bp of Annual GM% Expansion Opportunity Beyond 2021E**

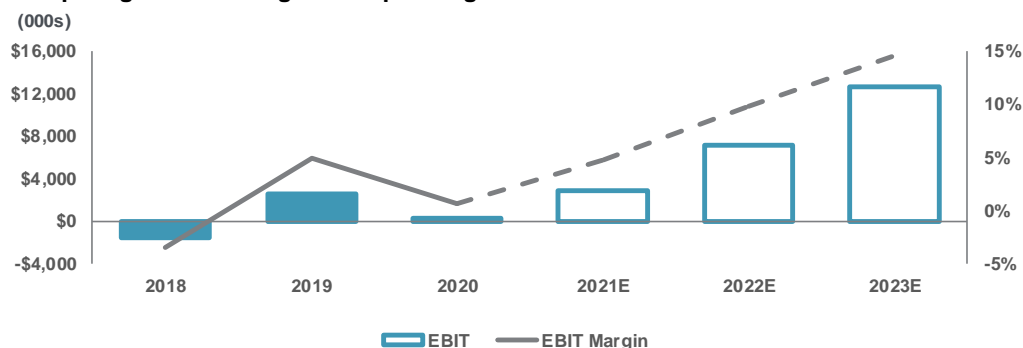


Sources: Company Reports, Piper Sandler Estimates

As for operating expenses and EBIT, we show below that management was able to turn EDAP profitable in 2019 and sustain that position in 2020 despite COVID-related headwinds. Considering the top-line improvements we see for the business over the next few years as HIFU gains greater commercial traction, there could be a nice path to profitability improvements from here. It's this mindset with which we're currently setting our projections today, but we don't want to rule out the potential for opex to rebase higher in the near term given the resources management plans to devote to advancing payer coverage and building a larger commercial infrastructure. If that's the route taken, we would see these investments as dollars well spent, and we suspect most investors would take a similar welcoming view. We'll look to management's commentary on the 1Q conference call in the coming weeks for additional color on the pace of spending, but we show below our projections as they currently sit today, including operating income and OM% of \$2.9M/4.8% in 2021, \$7.1M/9.8% in 2022, and \$12.6M/14.5% in 2023.

Exhibit 17

**Anticipating Inflection Higher in Operating Income and OM%**

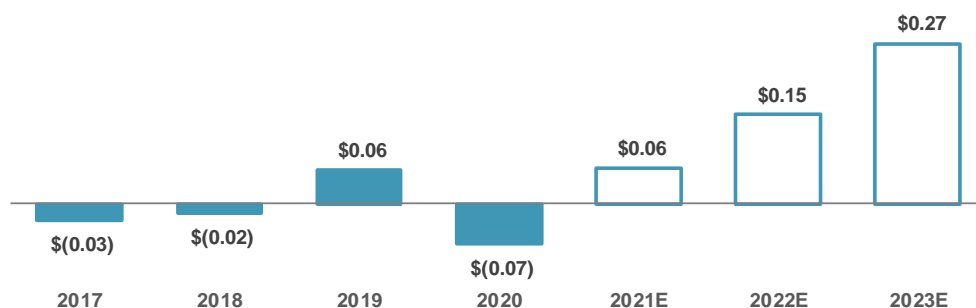


Sources: Company Reports, Piper Sandler Estimates

Finally for EPS, we’re expecting EDAP to return to being a positive EPS reporter this year, although we note this is partially dependent on the level of resources management elects to direct to accelerating its HIFU commercial plan in the U.S. Beyond 2021 and consistent with the financial progress we expect from the company over the next few years, we believe earnings should similarly trek higher in a steady fashion.

Exhibit 18

**We Expect EPS to Steadily Move Higher on the Back of U.S. HIFU Progress**



Sources: Company Reports, Piper Sandler Estimates

**Balance Sheet and Liquidity**

EDAP recently pre-announced 1Q results and noted at the time the company ended the period with €24.4M (\$28.6M) in cash on the balance sheet. After taking into account \$25.6M in net proceeds from the recent capital raise, we estimate the company has nearly \$55M in available cash on the balance sheet. This level of capital should give EDAP ample resources over the next few years to move more aggressively in developing the market for HIFU in the U.S., inclusive of securing formalized coverage policies for use of HIFU in prostate cancer and building a more robust commercial infrastructure.

From a debt perspective, the company currently has a very modest \$8.3M in debt on its balance sheet. While a majority of this debt is coming due this year (\$7.2M of the \$8.3M), we wouldn’t be surprised if management were to extend the maturity on this debt given the current rate environment, although EDAP’s cash position described above couple with modest annual FCF generation provides management the option to repay these loans if desired.



**Piper Sandler  
Estimates**

We're introducing estimates today for EDAP through FY'23, including revenue of \$60.3M in 2021, \$72.3M in 2022, and \$86.7M in 2023, GM% expansion of approximately 200bp in each of 2022 and 2023, OM% expansion of ~400-500bp over each of the next few years, and EPS of \$0.27 by 2023. We provide line item detail of these annual projections below, as well as how they compare vs. the Street. Worth nothing for 2023 in particular, the Street consists of a single model that looks to us to include an overestimation of growth and profitability for the company.

Exhibit 19

**Piper Sandler Estimates vs. Street**

	PIPER SANDLER		STREET	
	Value	Growth Y/Y %	Value	Growth Y/Y %
<b>2021</b>				
<b>Total Revenue</b>	<b>\$60,272</b>	<b>26.1%</b>	<b>\$61,800</b>	<b>29.3%</b>
Gross Profit	\$28,313	34.3%	\$29,800	41.3%
<i>Gross Margin</i>	47.0%	286bp	48.2%	411bp
Operating Income	\$2,876	830.8%	\$4,100	1226.9%
<i>Operating Margin</i>	4.8%	413bp	6.6%	599bp
<b>EPS</b>	<b>\$0.06</b>	<b>NM</b>	<b>\$0.13</b>	<b>NM</b>
<b>2022</b>				
<b>Total Revenue</b>	<b>\$72,303</b>	<b>20.0%</b>	<b>\$76,600</b>	<b>23.9%</b>
Gross Profit	\$35,469	25.3%	\$38,700	29.9%
<i>Gross Margin</i>	49.1%	208bp	50.5%	230bp
Operating Income	\$7,081	146.2%	\$9,900	141.5%
<i>Operating Margin</i>	9.8%	502bp	12.9%	629bp
<b>EPS</b>	<b>\$0.15</b>	<b>148.3%</b>	<b>\$0.28</b>	<b>115.4%</b>
<b>2023</b>				
<b>Total Revenue</b>	<b>\$86,690</b>	<b>19.9%</b>	<b>\$102,400</b>	<b>33.7%</b>
Gross Profit	\$44,131	24.4%	\$55,600	43.7%
<i>Gross Margin</i>	50.9%	185bp	54.3%	377bp
Operating Income	\$12,597	77.9%	\$28,300	185.9%
<i>Operating Margin</i>	14.5%	474bp	27.6%	1471bp
<b>EPS</b>	<b>\$0.27</b>	<b>80.2%</b>	<b>\$0.70</b>	<b>150.0%</b>

\*Street estimates include average of three estimates for '21/'22 and one estimate for '23

Sources: Company Reports, FactSet, Piper Sandler Estimates

**Management**

EDAP TMS is led by CEO Marc Oczachowski and CFO François Dietsch, two individuals who boast a collective 40 years of experience in various roles at the company. Mr. Oczachowski joined the company in 1997 as an area sales manager and held the role as COO from 2004-2007 before being named CEO. He's now served as EDAP's CEO for over 14 years, and also was appointed Chairman of the Board of Directors in March last year. Prior to joining EDAP, he worked as an area sales manager for Sodem Systems, a manufacturer of power tools for the orthopedic industry. He graduated from Lyon I University and from Institut Commercial de Lyon, France.

Mr. Dietsch joined EDAP in 2005 as an Internal Audit and Consolidation Manager, and served in various finance and accounting roles over the next decade. In 2015 he was promoted to his current CFO role of the company. Prior to joining EDAP he held finance positions at Valeo, a leading global supplier of components and systems to the automotive industry. He holds Master's Degrees in Management and Corporate Finance from University of Paris Dauphine.

EDAP TMS S.A. (EDAP)

Financial Statements  
Fiscal Year End: Dec 31  
(\$ in thousands)

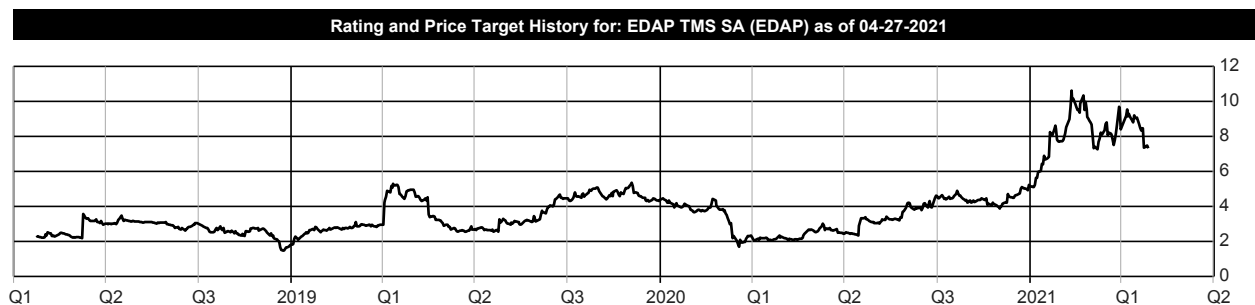
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4/27/2021

	2018	2019	1Q20 MAR	2Q20 JUN	3Q20 SEP	4Q20 DEC	2020	1Q21E MAR	2Q21E JUN	3Q21E SEP	4Q21E DEC	2021E	1Q22E MAR	2Q22E JUN	3Q22E SEP	4Q22E DEC	2022E	2023E
<b>Total Revenue</b>	\$ 46,002	\$ 50,231	\$ 8,396	\$ 10,267	\$ 11,160	\$ 18,348	\$ 47,805	\$ 12,277	\$ 13,923	\$ 13,799	\$ 20,274	\$ 60,272	\$ 14,572	\$ 16,705	\$ 16,665	\$ 24,360	\$ 72,303	\$ 86,690
Cost of Sales	26,153	26,732	5,018	5,470	6,470	9,953	26,716	7,038	7,393	7,458	10,070	31,959	8,060	8,499	8,669	11,606	36,834	42,560
<b>Gross Profit</b>	\$ 19,849	\$ 23,499	\$ 3,378	\$ 4,797	\$ 4,690	\$ 8,395	\$ 21,089	\$ 5,239	\$ 6,530	\$ 6,340	\$ 10,204	\$ 28,313	\$ 6,512	\$ 8,206	\$ 7,996	\$ 12,754	\$ 35,469	\$ 44,131
Research & Development Expense	4,825	4,173	1,150	1,027	1,289	1,718	5,159	1,473	1,531	1,518	1,662	6,185	1,676	1,671	1,667	1,705	6,718	7,672
SG&A Expense	16,640	16,857	3,839	3,434	3,748	4,622	15,621	4,481	4,873	4,830	5,069	19,252	5,100	5,346	5,500	5,725	21,670	23,862
<b>Operating Income</b>	\$ (1,616)	\$ 2,469	\$ (1,611)	\$ 336	\$ (347)	\$ 2,055	\$ 309	\$ (715)	\$ 125	\$ (7)	\$ 3,473	\$ 2,876	\$ (264)	\$ 1,190	\$ 830	\$ 5,324	\$ 7,081	\$ 12,597
Interest (Expense) Income, Net	950	(163)	(23)	(21)	(14)	(55)	(112)	(55)	(55)	(55)	(55)	(220)	(55)	(55)	(55)	(55)	(220)	(220)
Foreign Currency Loss and Other	640	149	319	(385)	(679)	(869)	(1,560)	-	-	-	-	-	-	-	-	-	-	-
Other (Expense) Income, net	1,590	(14)	296	(406)	(693)	(924)	(1,672)	(55)	(55)	(55)	(55)	(220)	(55)	(55)	(55)	(55)	(220)	(220)
<b>Pre-tax Income</b>	\$ (26)	\$ 2,455	\$ (1,315)	\$ (70)	\$ (1,040)	\$ 1,131	\$ (1,363)	\$ (770)	\$ 70	\$ (62)	\$ 3,418	\$ 2,656	\$ (319)	\$ 1,135	\$ 775	\$ 5,269	\$ 6,861	\$ 12,377
Income Tax Expense	424	758	128	124	145	197	592	(192)	18	(15)	854	664	(80)	284	194	1,317	1,715	3,094
<b>Net Income (Loss)</b>	\$ (450)	\$ 1,697	\$ (1,443)	\$ (194)	\$ (1,185)	\$ 934	\$ (1,955)	\$ (577)	\$ 53	\$ (46)	\$ 2,563	\$ 1,992	\$ (239)	\$ 851	\$ 582	\$ 3,952	\$ 5,146	\$ 9,283
<b>EPS</b>	\$ (0.02)	\$ 0.06	\$ (0.05)	\$ (0.01)	\$ (0.04)	\$ 0.03	\$ (0.07)	\$ (0.02)	\$ 0.00	\$ (0.00)	\$ 0.07	\$ 0.06	\$ (0.01)	\$ 0.02	\$ 0.02	\$ 0.11	\$ 0.15	\$ 0.27
Diluted Share Count	28,998	29,615	29,142	29,142	29,144	30,222	29,148	30,232	33,345	34,382	34,392	33,088	34,402	34,412	34,422	34,432	34,417	34,457
<b>Growth Analysis</b>																		
Revenue - as reported	12.9%	9.2%	-27.0%	-26.8%	-1.6%	37.5%	-4.8%	46.2%	35.6%	23.6%	10.5%	26.1%	18.7%	20.0%	20.8%	20.2%	20.0%	19.9%
Gross Profit	17.6%	18.4%	-38.8%	-32.6%	-8.7%	46.7%	-10.3%	55.1%	36.1%	35.2%	21.5%	34.3%	24.3%	25.7%	26.1%	25.0%	25.3%	24.4%
Research & Development Expense	9.1%	-13.5%	0.0%	-7.3%	32.2%	82.8%	23.6%	28.1%	49.1%	17.8%	-3.2%	19.9%	13.7%	9.1%	9.8%	2.6%	8.6%	14.2%
SG&A Expense	12.7%	1.3%	-7.2%	-17.2%	-3.3%	-1.5%	-7.3%	16.7%	41.9%	28.9%	9.7%	23.2%	13.8%	9.7%	13.9%	12.9%	12.6%	10.1%
Total Operating Expense	11.9%	-2.0%	-5.6%	-15.1%	3.8%	12.5%	-1.2%	19.3%	43.6%	26.0%	6.2%	22.4%	13.8%	9.6%	12.9%	10.4%	11.6%	11.1%
Operating Income	NM	NM	NM	-81.9%	NM	2235.2%	-87.5%	NM	-62.7%	NM	69.0%	830.8%	NM	849.5%	NM	53.3%	146.2%	77.9%
EPS	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	141.2%	NM	NM	1463.7%	NM	54.0%	148.3%	80.2%
<b>Margin Analysis</b>																		
Gross Margin	43.1%	46.8%	40.2%	46.7%	42.0%	45.8%	44.1%	42.7%	46.9%	45.9%	50.3%	47.0%	44.7%	49.1%	48.0%	52.4%	49.1%	50.9%
Research & Development Expense	10.5%	8.3%	13.7%	10.0%	11.6%	9.4%	10.8%	12.0%	11.0%	11.0%	8.2%	10.3%	11.5%	10.0%	10.0%	7.0%	9.3%	8.9%
SG&A Expense	36.2%	33.6%	45.7%	33.4%	33.6%	25.2%	32.7%	36.5%	35.0%	35.0%	25.0%	31.9%	35.0%	32.0%	33.0%	23.5%	30.0%	27.5%
Operating Margin	-3.5%	4.9%	-19.2%	3.3%	-3.1%	11.2%	0.6%	-5.8%	0.9%	-0.1%	17.1%	4.8%	-1.8%	7.1%	5.0%	21.9%	9.8%	14.5%
Net Income	-1.0%	3.4%	-17.2%	-1.9%	-10.6%	5.1%	-4.1%	-4.7%	0.4%	-0.3%	12.6%	3.3%	-1.6%	5.1%	3.5%	16.2%	7.1%	10.7%
<b>Other Assumptions</b>																		
Tax Rate	-1630.8%	30.9%	-9.7%	-177.1%	-13.9%	17.4%	-	25%	25%	25%	25%	-	25%	25%	25%	25%	-	-
Interest Expense	1,590	(14)	296	(406)	(693)	(924)	-	-	-	-	-	-	-	-	-	-	-	-
Diluted Shares	28,998	29,615	29,142	29,142	29,144	30,222	-	10	3,113	1,038	10	-	10	10	10	10	-	-

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- R: Resuming Coverage
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- D: Discontinuing Coverage
- S: Suspending Coverage
- OW: Overweight
- N: Neutral
- UW: Underweight
- NA: Not Available
- UR: Under Review

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<b>HOLD [N]</b>	<b>327</b>	<b>35.54</b>	<b>63</b>	<b>19.27</b>
<b>SELL [UW]</b>	<b>7</b>	<b>0.76</b>	<b>0</b>	<b>0.00</b>

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